

# EXHIBIT B



Page 2	Page 4
<p>1 DEPOSITION OF MICHAEL KARRAM, M.D.  2 APPEARANCES  3 ---  4 JOSEPH J. ZONIES, ESQUIRE  REILLY POZNER LLP  5 1900 Sixteenth Street, Suite 1700  Denver, Colorado 80202  6 303-893-6100  jzonies@rplaw.com,  7 and  8 JAMES W. LAMPKIN, III, ESQUIRE (VIA TELECONFERENCE)  9 WESLEY CHADWICK COOK, ESQUIRE (VIA TELECONFERENCE)  BEASLEY, ALLEN, CROW, METHVIN, PORTIS &amp; MILES, P.C.  10 218 Commerce Street  Montgomery, Alabama 36104  11 334-269-2343  james.lampkin@beasleyallen.com  12 chad.cook@beasleyallen.com  13 On behalf of the Plaintiffs.  14  DOUGLAS J. DIPAOLO, M.D., ESQUIRE  15 BUTLER SNOW LLP  1020 Highland Colony Parkway, Suite 1400  16 Ridgeland, Mississippi 39157  601-948-5711  17 douglas.dipaola@butlersnow.com,  18 On behalf of the Defendants.  19  20 ALSO PRESENT:  21 Shea Shaver, Reilly Pozner  22  23 ---  24</p>	<p>1 DEPOSITION OF MICHAEL KARRAM, M.D.  2 INDEX TO EXHIBITS  3 EXHIBIT DESCRIPTION PAGE  4 1 NOTICE TO TAKE DEPOSITION OF 7  DR. MICHAEL KARRAM  5  6 2 GENERAL TVT REPORT PREPARED BY 7  MICHAEL KARRAM, M.D.  7 3 CURRICULUM VITAE OF MICHAEL 7  KARRAM, M.D.  8  9 4 DOCUMENT ENTITLED, "RELIANCE 7  LIST, IN ADDITION TO MATERIALS  10 REFERENCED IN REPORT, MDL  11 WAVE 1"  12 CURRICULUM VITAE OF MICHAEL 9  KARRAM, M.D.  13  14 6 GENERAL TVT REPORT PREPARED BY 10  MICHAEL KARRAM, M.D.  15 7 FEDERAL REGISTER, VOLUME 70, 67  NO. 147, TUESDAY, AUGUST 2,  2005, NOTICES, PAGES  16 44376-44387  17  18 8 ARTICLE ENTITLED, "RETROPUBIC 96  VERSUS TRANSOBTURATOR  19 MIDURETHRAL SLINGS FOR STRESS  20 INCONTINENCE"  21 9 ARTICLE ENTITLED, "TENSION-FREE 108  VAGINAL TAPE (TVT) IN WOMEN  22 WITH RECURRENT STRESS URINARY  23 INCONTINENCE - A LONG-TERM  24 FOLLOW UP"  10 ARTICLE ENTITLED, "A THREE-YEAR 110  FOLLOW UP OF TENSION FREE  VAGINAL TAPE FOR SURGICAL  TREATMENT OF FEMALE STRESS  URINARY INCONTINENCE"</p>
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<p>1 Tuesday Morning Session  March 29, 2016  2 10:02 a.m.  3 ---  4 STIPULATIONS  5 It is stipulated by and among counsel for the  6 respective parties that the deposition of MICHAEL  7 KARRAM, M.D., a Witness herein, called by the Plaintiffs  8 under the applicable Federal Rules of Civil Procedure,  9 may be taken at this time in stenotype by the Notary,  10 pursuant to notice; that said deposition may thereafter  11 be transcribed by the Notary out of the presence of the  12 witness; that proof of the official character and  13 qualification of the Notary is waived; that the witness  14 may sign the transcript of his deposition before a  15 Notary other than the Notary taking his deposition; said  16 deposition to have the same force and effect as though  17 signed before the Notary taking it.  18 ---  19  20  21  22  23  24</p>	<p>1 INDEX TO EXHIBITS (CONT'D)  2 EXHIBIT DESCRIPTION PAGE  3 11 INVITATION FOR ADVANCED PELVIC 128  FLOOR COURSE, COURSE 2, BATES-  4 STAMPED ETH.MESH.00789838  5 12 INVITATION FOR ADVANCED PELVIC 130  FLOOR COURSE, BATES-STAMPED  6 ETH.MESH.01678144  7 13 SPREADSHEET BATES-STAMPED 132  ETH.MESH.04181701  8  9  10  11  12  13  14  15  16  17  18  19  20  21  22  23  24</p>

<p style="text-align: right;">Page 6</p> <p>1 INDEX TO EXAMINATION</p> <p>2 WITNESS PAGE</p> <p>3 MICHAEL KARRAM, M.D.</p> <p>4 EXAMINATION BY MR. ZONIES: 7</p> <p>5 EXAMINATION BY MR. DIPOLA: 140</p> <p>6 FURTHER EXAMINATION BY MR. ZONIES: 143</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 8</p> <p>1 BY MR. ZONIES:</p> <p>2 Q. Good morning, sir. Could you please state</p> <p>3 your name for the record.</p> <p>4 A. Michael Karram.</p> <p>5 Q. And you are a medical doctor?</p> <p>6 A. Yes, I am.</p> <p>7 Q. What is your specialty?</p> <p>8 A. Gynecology and urogynecology.</p> <p>9 Q. How long have you been practicing medicine?</p> <p>10 A. Since 1984.</p> <p>11 Q. Sir, my name is Joe Zonies. I represent the</p> <p>12 Plaintiffs in this matter.</p> <p>13 Do you understand what your role is here</p> <p>14 today?</p> <p>15 A. Yes, I do.</p> <p>16 Q. What is it?</p> <p>17 A. To testify on a report that I prepared on a</p> <p>18 procedure used for stress urinary incontinence.</p> <p>19 Q. On whose behalf are you testifying?</p> <p>20 A. On behalf of the defense.</p> <p>21 Q. And who is that?</p> <p>22 A. Would be Ethicon Endo-Surgery or J&amp;J.</p> <p>23 Q. Do you have an understanding of who hired you?</p> <p>24 A. The law firm.</p>
<p style="text-align: right;">Page 7</p> <p>1 ---</p> <p>2 PROCEEDINGS</p> <p>3 ---</p> <p>4 NOTICE TO TAKE DEPOSITION OF</p> <p>5 DR. MICHAEL KARRAM WAS MARKED AS</p> <p>6 EXHIBIT NO. 1.</p> <p>7 ---</p> <p>8 GENERAL TVT REPORT PREPARED BY</p> <p>9 MICHAEL KARRAM, M.D. WAS MARKED AS</p> <p>10 EXHIBIT NO. 2.</p> <p>11 ---</p> <p>12 CURRICULUM VITAE OF MICHAEL KARRAM,</p> <p>13 M.D. WAS MARKED AS EXHIBIT NO. 3.</p> <p>14 ---</p> <p>15 DOCUMENT ENTITLED, "RELIANCE LIST,</p> <p>16 IN ADDITION TO MATERIALS REFERENCED</p> <p>17 IN REPORT, MDL WAVE 1" WAS MARKED</p> <p>18 AS EXHIBIT NO. 4.</p> <p>19 ---</p> <p>20 MICHAEL KARRAM, M.D.</p> <p>21 being by me first duly sworn, as hereinafter certified,</p> <p>22 deposes and says as follows:</p> <p>23 EXAMINATION</p> <p>24</p>	<p style="text-align: right;">Page 9</p> <p>1 Q. Which law firm?</p> <p>2 A. Butler Snow.</p> <p>3 Q. Have you ever worked for that law firm before?</p> <p>4 A. No.</p> <p>5 Q. I've had marked Exhibit 1. Have you seen this</p> <p>6 document before entitled "Notice to Take Deposition of</p> <p>7 Dr. Michael Karram"?</p> <p>8 A. I have not.</p> <p>9 Q. Can you turn to page 6.</p> <p>10 A. Okay.</p> <p>11 Q. Do you see where it says "Schedule A"?</p> <p>12 A. Yes.</p> <p>13 Q. Have you ever reviewed this Schedule A before?</p> <p>14 A. No.</p> <p>15 Q. Did you bring with you No. 1, a copy of your</p> <p>16 current curriculum vitae?</p> <p>17 A. I did.</p> <p>18 Q. Do you have that with you?</p> <p>19 A. Yes.</p> <p>20 Q. Can I see that, please? Thank you.</p> <p>21 MR. ZONIES: Go ahead and mark that, please.</p> <p>22 ---</p> <p>23 CURRICULUM VITAE OF MICHAEL KARRAM,</p> <p>24 M.D., WAS MARKED AS EXHIBIT NO. 5.</p>

<p style="text-align: right;">Page 10</p> <p>1               ---</p> <p>2       Q. Could you describe, please, what has been</p> <p>3 marked as Exhibit 5.</p> <p>4       A. My updated CV.</p> <p>5       Q. When did you update that CV?</p> <p>6       A. Last time was maybe about three months ago.</p> <p>7       Q. Three months ago?</p> <p>8       A. Correct.</p> <p>9       Q. Back on Exhibit 1, the Notice of Deposition,</p> <p>10 did you have any documents or bring any documents with</p> <p>11 you that are correspondence, notes, videos, CDs, DVDs</p> <p>12 with your materials that were provided to you or which</p> <p>13 relate to your opinions?</p> <p>14       A. No. The only thing I brought was my report.</p> <p>15       Q. Okay. Could I go ahead and grab that as well?</p> <p>16       A. Sure.</p> <p>17       Q. Thank you.</p> <p>18               ---</p> <p>19               GENERAL TVT REPORT PREPARED BY</p> <p>20               MICHAEL KARRAM, M.D., WAS MARKED AS</p> <p>21               EXHIBIT NO. 6.</p> <p>22               ---</p> <p>23       Q. Doctor, I'm handing you what has been marked</p> <p>24 as Exhibit 6, which is a copy of your report that you</p>	<p style="text-align: right;">Page 12</p> <p>1       A. Right.</p> <p>2       Q. What are those documents?</p> <p>3       A. Those, I think, are documents that relate to</p> <p>4 Ethicon products or information that they put in their</p> <p>5 prof ed material that we utilized for some of our</p> <p>6 cadaver courses.</p> <p>7       Q. Did you choose which documents to put on that</p> <p>8 reliance list?</p> <p>9       A. I just okayed those.</p> <p>10       Q. You okayed the list that was presented to you?</p> <p>11       A. Right.</p> <p>12       Q. Did you review every single one of those</p> <p>13 documents that are, for lack of a better word, internal</p> <p>14 Ethicon documents?</p> <p>15               MR. DIPOLA: Object to form.</p> <p>16       A. I did not review any internal Ethicon reports.</p> <p>17       Q. You haven't reviewed any internal Ethicon</p> <p>18 documents; is that fair?</p> <p>19       A. Correct.</p> <p>20       Q. Have you reviewed any of Ethicon's design</p> <p>21 specifications for any of its products?</p> <p>22       A. Only what they incorporated in their IFUs.</p> <p>23       Q. Have you reviewed any internal Ethicon emails?</p> <p>24       A. No.</p>
<p style="text-align: right;">Page 11</p> <p>1 brought with you; is that right?</p> <p>2       A. That is correct.</p> <p>3       Q. And attached to that is a reliance list as</p> <p>4 well; is that right?</p> <p>5       A. Yes.</p> <p>6       Q. Did you prepare the reliance list?</p> <p>7       A. Yes.</p> <p>8       Q. How did you choose what materials you wanted</p> <p>9 to review?</p> <p>10       A. It was material that I used from textbooks,</p> <p>11 from journals, from previous information that I've</p> <p>12 utilized with this type of procedure, scientific data,</p> <p>13 things that I've used for lectures, talks, those types</p> <p>14 of things.</p> <p>15       Q. Have you reviewed any depositions of any</p> <p>16 Ethicon employees in preparation of your report or for</p> <p>17 this deposition?</p> <p>18       A. No.</p> <p>19       Q. Have you reviewed or attended any trials</p> <p>20 against Ethicon?</p> <p>21       A. No.</p> <p>22       Q. In your reliance materials, there are a</p> <p>23 significant number of documents marked ETH.MESH.some</p> <p>24 number; is that right?</p>	<p style="text-align: right;">Page 13</p> <p>1       Q. Have you reviewed any other expert witnesses'</p> <p>2 reports in this litigation?</p> <p>3       A. I reviewed Dr. Ostergard's deposition.</p> <p>4       Q. His deposition?</p> <p>5       A. Yes.</p> <p>6       Q. Anything else?</p> <p>7       A. I reviewed a Prolift report from a Dr. -- I</p> <p>8 think it's Pramudji. She's a urologist in Houston.</p> <p>9       Q. And that was the report?</p> <p>10       A. That was the report.</p> <p>11       Q. Did you review any other expert reports of</p> <p>12 either Plaintiffs' or Defendants' experts.</p> <p>13       A. No.</p> <p>14       Q. Did you review any other depositions other</p> <p>15 than Ostergard's deposition of either Plaintiffs' or</p> <p>16 Defendants' experts?</p> <p>17       A. No.</p> <p>18       Q. Why did you choose to review Ostergard's</p> <p>19 deposition?</p> <p>20       A. It was sent to me.</p> <p>21       Q. Do you know Dr. Ostergard?</p> <p>22       A. I do.</p> <p>23       Q. How well?</p> <p>24       A. Not very well now. Earlier in his career, I</p>

<p style="text-align: right;">Page 14</p> <p>1 knew him -- I did a rotation with him.</p> <p>2 Q. Why did you choose to review the Prolift</p> <p>3 report?</p> <p>4 A. It was sent to me.</p> <p>5 Q. Of the materials that were sent to you, did</p> <p>6 you have any follow-ups or requests for additional</p> <p>7 information?</p> <p>8 A. No.</p> <p>9 Q. If you look back at the Notice of Deposition,</p> <p>10 Exhibit 1, No. 8, any and all documents, including time</p> <p>11 sheets, invoices, time records, billing records. Did</p> <p>12 you bring anything of that nature today?</p> <p>13 A. No.</p> <p>14 Q. Have you submitted invoices for your work?</p> <p>15 A. I have.</p> <p>16 Q. Is there a reason you didn't bring those</p> <p>17 invoices today?</p> <p>18 A. I wasn't aware that I needed to bring them.</p> <p>19 Q. And that's in part because you never saw this?</p> <p>20 A. I never saw this.</p> <p>21 Q. Did you bring with you what's described in</p> <p>22 Exhibit 1, No. 10, "Any and all documents, including</p> <p>23 consulting agreements" with Ethicon?</p> <p>24 A. I did not.</p>	<p style="text-align: right;">Page 16</p> <p>1 Q. Is there a difference in your mind between the</p> <p>2 consulting and the preceptorships?</p> <p>3 A. Preceptorships, I would think, would be</p> <p>4 somebody who comes to my institution and watches me do</p> <p>5 surgery, or I go to their institution and watch them do</p> <p>6 surgery. That, I think, is -- I would consider</p> <p>7 different than teaching a prof ed course.</p> <p>8 Q. What is the purpose of a preceptorship?</p> <p>9 A. It's a physician is learning or has learned or</p> <p>10 has issues or questions or just wants a more experienced</p> <p>11 surgeon there when they're performing the procedure.</p> <p>12 That's the purpose of a preceptorship.</p> <p>13 Q. Were you compensated by Ethicon for</p> <p>14 preceptorships?</p> <p>15 A. Yes.</p> <p>16 Q. Did you have an agreement with Ethicon about</p> <p>17 how much you would be compensated for preceptorships?</p> <p>18 A. That was in the agreement, yes. The amount</p> <p>19 was in the agreement.</p> <p>20 Q. Was that same agreement also for professional</p> <p>21 education?</p> <p>22 A. I'm not sure. They might have been separate</p> <p>23 agreements, but it was the same type of agreement where</p> <p>24 the amount would be in the agreement.</p>
<p style="text-align: right;">Page 15</p> <p>1 MR. DIPOLA: Object to form.</p> <p>2 Q. Did you have consulting agreements with</p> <p>3 Ethicon?</p> <p>4 MR. DIPOLA: Object to form.</p> <p>5 A. In the past, yes.</p> <p>6 Q. How many do you think you had?</p> <p>7 MR. DIPOLA: Object again.</p> <p>8 A. Could you describe or explain what a</p> <p>9 consulting agreement would be?</p> <p>10 Q. Sure. You've done consulting work with</p> <p>11 Ethicon; is that correct?</p> <p>12 A. If you consider teaching courses, cadaver</p> <p>13 courses, and things like that, yes.</p> <p>14 Q. Have you done preceptorships?</p> <p>15 A. Yes.</p> <p>16 Q. You've also taught professional education</p> <p>17 programs?</p> <p>18 A. Yes.</p> <p>19 Q. Have you spoken at any events on behalf of</p> <p>20 Ethicon?</p> <p>21 A. No.</p> <p>22 Q. Were you compensated by Ethicon for your time</p> <p>23 as a consultant?</p> <p>24 A. In those teaching endeavors, yes.</p>	<p style="text-align: right;">Page 17</p> <p>1 Q. And you've been consulting with Ethicon for</p> <p>2 how long?</p> <p>3 A. Probably in the neighborhood of -- started</p> <p>4 around 2004, 2005, something in that neighborhood, until</p> <p>5 just recently, maybe the last two or three years, when</p> <p>6 they stopped doing prof ed and preceptorships and things</p> <p>7 like that. Maybe it's been four years, the past four</p> <p>8 years.</p> <p>9 Q. Prior to 2004, did you do any work for</p> <p>10 Ethicon, consulting or preceptorships?</p> <p>11 A. Not that I'm aware of.</p> <p>12 Q. Is it your recollection that you would have</p> <p>13 annual contracts with Ethicon for purposes of your</p> <p>14 preceptorships?</p> <p>15 A. Yes.</p> <p>16 Q. Is it also your understanding that you would</p> <p>17 have annual contracts with Ethicon that would cover your</p> <p>18 professional education work?</p> <p>19 A. Yes.</p> <p>20 Q. And you're not certain if you had two</p> <p>21 different ones or if those were included in the same?</p> <p>22 A. That's correct.</p> <p>23 Q. Is it fair to say that from 2004 through --</p> <p>24 you think 2011 is fair for the last time you did it?</p>

<p style="text-align: right;">Page 18</p> <p>1 A. We're at 2016 now. I would say that's a rough  2 estimate, yes.  3 Q. 2011, 2012?  4 A. Something like that.  5 Q. Is it fair to say that between the years 2004  6 and 2012, approximately, that Ethicon paid you  7 compensation for work as a preceptor and as a  8 consultant?  9 MR. DIPOLA: Object to form.  10 A. Correct.  11 Q. Do you have a sense, as you sit here today,  12 how much that amounted to each of those years?  13 A. As a total amount, no. I can say, if I  14 recollect correctly, that when I did a program, it was a  15 flat fee, something in the neighborhood of \$2,500 to  16 \$3,000 for a weekend course, which would be Friday,  17 Saturday, and sometimes Sunday morning.  18 Q. And that's for professional education?  19 A. Professional education and the preceptorships,  20 I think, were in the neighborhood of either 1,000 or  21 1,500 dollars, plus travel expenses if you had to go  22 someplace else.  23 Q. Do you have a sense of between 2004 and 2012  24 how many professional education courses you've taught on</p>	<p style="text-align: right;">Page 20</p> <p>1 file?  2 A. I doubt it. Maybe some of them.  3 Q. But you haven't done anything to look for  4 those?  5 A. I have not. Sorry. I have not.  6 Q. All it took was a look.  7 A. I know.  8 Q. If you look at Exhibit 1 on page 8, No. 12,  9 "All correspondence, memoranda, emails, and any other  10 documentation reflecting communications (including  11 written, electronic or oral) with any employees of  12 Defendants related to any female pelvic mesh product  13 sold by Ethicon."  14 Do you believe that you've ever corresponded,  15 either in writing or by email, with Ethicon employees  16 aside from the contract?  17 MR. DIPOLA: Object to form.  18 Q. Aside from the --  19 A. Where is this again on page 8?  20 Q. Page 8, No. 12.  21 A. Oh, okay.  22 Q. Do you see that?  23 A. Yes.  24 Q. So my question, Doctor, is, aside from the</p>
<p style="text-align: right;">Page 19</p> <p>1 behalf of Ethicon?  2 A. Again, as a rough estimate, I would say I  3 probably did maybe two to three a year.  4 Q. What about preceptorships?  5 A. That would be included in that two to three a  6 year. It would either be a prof ed or a preceptorship.  7 Q. When a prof ed was out of town, Ethicon would  8 also pay for your travel expenses; is that right?  9 A. That's correct.  10 Q. And you book your travel through Ethicon's  11 travel agency; is that right?  12 A. Yes.  13 Q. Aside from the consulting and the  14 preceptorships, did you receive any other compensation  15 from Ethicon?  16 A. No.  17 Q. How did you receive the contracts from  18 Ethicon? Was it electronically, or did they send them  19 to you?  20 MR. DIPOLA: Object to form.  21 A. They sent them to me, and I would sign them  22 and send them back, and they would send me a signed  23 copy.  24 Q. You think you still have those somewhere in a</p>	<p style="text-align: right;">Page 21</p> <p>1 contracts we just discussed, do you believe that over  2 any time period that you've communicated in writing or  3 by email with any Ethicon employees?  4 A. No.  5 Q. If you look at No. 14, it requests any  6 documents related to professional education, including  7 PowerPoints, course materials. Do you have in your  8 possession documents like that?  9 A. No.  10 Q. Do you have any electronically, any of your  11 PowerPoint presentations that you've used for your  12 professional education?  13 A. Do I have them with me?  14 Q. Not with you. Do you have those on a computer  15 or at home or in your office?  16 A. I probably have some.  17 Q. Did you do anything to look for those and  18 bring those today?  19 A. No.  20 Q. And, again, that's because you didn't know you  21 were supposed to with this Exhibit 1?  22 A. Right.  23 Q. I notice in your report there are some what  24 appear to be screenshots --</p>



<p style="text-align: right;">Page 22</p> <p>1 A. Um-hmm.</p> <p>2 Q. -- or pictures of a computer.</p> <p>3 A. Um-hmm.</p> <p>4 Q. Yes?</p> <p>5 A. Yes. Sorry. Yes.</p> <p>6 Q. Can you tell me what those are?</p> <p>7 A. Those are slides that I use in presentations,</p> <p>8 and they demonstrate certain data for certain issues.</p> <p>9 Q. Are those slides that you would have actually</p> <p>10 used in your professional education?</p> <p>11 A. In some of them, yes.</p> <p>12 Q. Are those slides that you created, or were</p> <p>13 those provided to you by Ethicon?</p> <p>14 A. Actually, the slides that I used in my report</p> <p>15 were not Ethicon slides. They were somebody else's</p> <p>16 slides, another surgeon's slides.</p> <p>17 Q. Do you know whose those were?</p> <p>18 A. Mark Walters.</p> <p>19 Q. Why did you have Mark Walters' slides?</p> <p>20 A. Because we were doing a combined presentation</p> <p>21 to urogyn fellows, and he was giving the talk to the</p> <p>22 urogyn fellows, and those were some of the updated</p> <p>23 slides he had in his presentation.</p> <p>24 Q. Do you know when that presentation was given?</p>	<p style="text-align: right;">Page 24</p> <p>1 Exhibit 3. This was the CV that was provided to us with</p> <p>2 your report. Is that an accurate and up-to-date CV, the</p> <p>3 same as Exhibit 5?</p> <p>4 A. Didn't you give me one before?</p> <p>5 Q. You brought one.</p> <p>6 A. Oh, I brought one. Okay. Yes.</p> <p>7 Q. That's up to date?</p> <p>8 A. Um-hmm.</p> <p>9 Q. Yes?</p> <p>10 A. Yes, yes.</p> <p>11 Q. When were you first hired to work as an expert</p> <p>12 in this litigation?</p> <p>13 A. I was asked to review some records on a</p> <p>14 patient sometime last year.</p> <p>15 Q. In 2015?</p> <p>16 A. Yes. Maybe even 2014. I don't know the exact</p> <p>17 date.</p> <p>18 Q. Is it one of the three patients that you're</p> <p>19 noticed for today and tomorrow?</p> <p>20 MR. DIPOLA: Object to form.</p> <p>21 A. I think it's two patients for tomorrow. And,</p> <p>22 no, it's not.</p> <p>23 Q. So it was two patients, but not the ones who</p> <p>24 you're being deposed on?</p>
<p style="text-align: right;">Page 23</p> <p>1 A. Maybe five years ago.</p> <p>2 Q. Was that an Ethicon-sanctioned event?</p> <p>3 A. It had nothing to do with Ethicon.</p> <p>4 Q. Have you ever done any clinical trials or</p> <p>5 studies that were funded by Ethicon?</p> <p>6 A. No.</p> <p>7 Q. Even for Thermachoice?</p> <p>8 A. Correct.</p> <p>9 Q. Have you ever done any clinical studies or --</p> <p>10 clinical trials or studies related to any Ethicon</p> <p>11 device, even if not funded by Ethicon?</p> <p>12 A. No.</p> <p>13 Q. I've marked as Exhibit 2 our copy of your</p> <p>14 report in this matter.</p> <p>15 A. Okay.</p> <p>16 Q. Can you take a look at that and make sure that</p> <p>17 that's your report.</p> <p>18 A. Yes.</p> <p>19 Q. There's not a date of when you signed this.</p> <p>20 Do you have a sense, Doctor, of when you would have</p> <p>21 executed this report?</p> <p>22 A. It should have been -- let's see. We are in</p> <p>23 March. Early February.</p> <p>24 Q. I'm going to hand you what has been marked as</p>	<p style="text-align: right;">Page 25</p> <p>1 A. No. It was one patient, but it wasn't the</p> <p>2 ones I'm being deposed on.</p> <p>3 Q. Got it. Thank you.</p> <p>4 When were you first asked to prepare the</p> <p>5 report that's Exhibit 2 in this case?</p> <p>6 A. It would have been about four or five months</p> <p>7 ago.</p> <p>8 Q. Who asked you to do that?</p> <p>9 A. Butler Snow.</p> <p>10 Q. Tell me how long you worked on that report.</p> <p>11 A. Well, can I get a calculator?</p> <p>12 Q. Absolutely.</p> <p>13 A. I can tell you based on what I submitted.</p> <p>14 Let's see. The report was 50 -- probably about 65</p> <p>15 hours.</p> <p>16 Q. And you know that based upon how much you</p> <p>17 invoiced?</p> <p>18 A. Correct.</p> <p>19 Q. What were your total invoices?</p> <p>20 A. So far my first invoice was for 28,000. I'm</p> <p>21 pretty sure that was it. And then I just submitted</p> <p>22 another one for 9,000.</p> <p>23 Q. So you've only submitted two invoices so far?</p> <p>24 A. That's correct.</p>



<p style="text-align: right;">Page 26</p> <p>1 Q. The 28,000, did that cover everything up to</p> <p>2 and including the final version of your report?</p> <p>3 MR. DIPOLA: Object to form.</p> <p>4 A. Yes.</p> <p>5 Q. Then what was the 9,000 for?</p> <p>6 A. Reviewing the same reports for today's</p> <p>7 deposition, reviewing more information on the patients</p> <p>8 that we're going to talk about tomorrow, reviewing</p> <p>9 Dr. Ostergard's deposition and some other materials that</p> <p>10 were provided.</p> <p>11 Q. And you just invoiced for that \$9,000?</p> <p>12 A. Correct.</p> <p>13 Q. Is that invoice -- does it have that type of</p> <p>14 detail that you just discussed?</p> <p>15 MR. DIPOLA: Object to form.</p> <p>16 A. Yes.</p> <p>17 Q. It says what you were doing, and does it say</p> <p>18 how long you took reviewing Ostergard's deposition, for</p> <p>19 example?</p> <p>20 A. Yes.</p> <p>21 Q. The \$28,000, did that include your work on not</p> <p>22 just Exhibit 2 but also the three case-specific expert</p> <p>23 reports that --</p> <p>24 MR. DIPOLA: Object to form.</p>	<p style="text-align: right;">Page 28</p> <p>1 A. Yes.</p> <p>2 Q. Did you do a case-specific report on</p> <p>3 Dr. Sharon Boggs?</p> <p>4 A. Yes.</p> <p>5 Q. Margaret Kirkpatrick?</p> <p>6 A. Yes.</p> <p>7 Q. Paula Kriz?</p> <p>8 A. Yes.</p> <p>9 Q. Miranda Patterson?</p> <p>10 A. Yes.</p> <p>11 Q. Any other expert reports that you've issued</p> <p>12 aside from those six and the general report?</p> <p>13 A. No.</p> <p>14 Q. Is your time, your 65 hours, does that include</p> <p>15 your case-specific report and work on all six of those</p> <p>16 cases, as well as your general report?</p> <p>17 A. Yes.</p> <p>18 Q. Does your 65 hours include work on any other</p> <p>19 cases?</p> <p>20 A. No.</p> <p>21 Q. What hourly rate do you bill?</p> <p>22 A. \$500 an hour.</p> <p>23 Q. For all types of work?</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 27</p> <p>1 Q. -- have been provided to you?</p> <p>2 A. Two case-specific reports, yes.</p> <p>3 Q. Is your invoice broken out by which case you</p> <p>4 were working on?</p> <p>5 A. Yes.</p> <p>6 Q. Is it also separately broken out by how much</p> <p>7 time you spent on what we'll call your general report?</p> <p>8 A. Yes.</p> <p>9 Q. Do you know how much time you spent on the</p> <p>10 general report?</p> <p>11 A. No, I don't know exactly.</p> <p>12 Q. Some portion of that 65 hours, however?</p> <p>13 A. Correct.</p> <p>14 Q. If you turn back to Exhibit 1, Doctor. Do you</p> <p>15 have that in front of you?</p> <p>16 A. Yes.</p> <p>17 Q. You see in what we call the caption there are</p> <p>18 a number of cases listed?</p> <p>19 A. Correct.</p> <p>20 Q. Did you do a case-specific report on Donna</p> <p>21 Massey's case?</p> <p>22 A. Yes.</p> <p>23 Q. Did you do a case-specific report on Thelma</p> <p>24 Wright's case?</p>	<p style="text-align: right;">Page 29</p> <p>1 Q. Exhibit 2 is your general report; is that</p> <p>2 right?</p> <p>3 A. Yes.</p> <p>4 Q. Can you describe, please, what that is?</p> <p>5 A. This is a report that I put together</p> <p>6 discussing stress urinary incontinence, the treatments</p> <p>7 of stress urinary incontinence, the history and the</p> <p>8 evolution of the management of stress urinary</p> <p>9 incontinence, and addressing some issues as it relates</p> <p>10 to slings in the treatment of stress urinary</p> <p>11 incontinence.</p> <p>12 Q. What products would you say that report</p> <p>13 covers, what Ethicon products?</p> <p>14 A. TVT Retropubic, TVT-O, TVT Abbrevio; three.</p> <p>15 Q. Those three products?</p> <p>16 A. Those three products.</p> <p>17 Q. Does that report in your mind cover or have</p> <p>18 you issued an opinion on the TVT Secur?</p> <p>19 A. No.</p> <p>20 MR. DIPOLA: Object to form.</p> <p>21 Q. Does that report cover or have you issued an</p> <p>22 opinion on TVT Exact?</p> <p>23 A. That would be retropubic.</p> <p>24 Q. So you believe that this also does Exact in</p>

<p style="text-align: right;">Page 30</p> <p>1 addition to TVT Retropubic?</p> <p>2 A. Correct.</p> <p>3 Q. Have you ever used TVT Secur?</p> <p>4 A. I have.</p> <p>5 Q. When did you first start using TVT or Ethicon</p> <p>6 stress urinary incontinence products?</p> <p>7 A. 1998.</p> <p>8 Q. How were you trained?</p> <p>9 A. My brother trained me.</p> <p>10 Q. Was that in a formal course or just brothers?</p> <p>11 A. That was -- we were residents together, and we</p> <p>12 worked at the same hospital together, so it was a</p> <p>13 surgeon-surgeon training.</p> <p>14 Q. Like a preceptorship, in essence?</p> <p>15 MR. DIPOLA: Object to the form.</p> <p>16 A. Not really. Surgeon-surgeon.</p> <p>17 Q. Where did that take place?</p> <p>18 A. Good Samaritan Hospital here in Cincinnati.</p> <p>19 Q. Have you ever published in a peer-reviewed</p> <p>20 journal?</p> <p>21 A. Yes.</p> <p>22 Q. What publication and what journal?</p> <p>23 A. You can see there are some pharmaceutical data</p> <p>24 that I published or that I was part of studies in my CV</p>	<p style="text-align: right;">Page 32</p> <p>1 A. Correct.</p> <p>2 Q. On your CV, Exhibit 3, you have listed under</p> <p>3 "Employment" -- do you see that section, "Employment"?</p> <p>4 A. Yes.</p> <p>5 Q. Private practice at Seven Hills Women's Health</p> <p>6 Centers --</p> <p>7 A. Yes.</p> <p>8 Q. -- from 1984 to the present, correct?</p> <p>9 A. No. I was in private practice from 1984 until</p> <p>10 1998 by myself. Then I joined Seven Hills in 1998.</p> <p>11 That's when Seven Hills came together. So then I was</p> <p>12 part of a large single-specialty group which is called</p> <p>13 Seven Hills.</p> <p>14 Q. How large is Seven Hills?</p> <p>15 A. We have 42 physicians in our group.</p> <p>16 Q. What type of practice does that range?</p> <p>17 A. It's mainly obstetrics and gynecology. We</p> <p>18 also have some breast surgeons that are part of our</p> <p>19 group.</p> <p>20 Q. It says from 1988 to 2006 you were a</p> <p>21 consultant with Hilltop Research. What is Hilltop</p> <p>22 Research?</p> <p>23 A. Hilltop Research was a research company here</p> <p>24 in town that did a lot of these studies that I was</p>
<p style="text-align: right;">Page 31</p> <p>1 list at the end. Some of those articles went into some</p> <p>2 peer-reviewed journals.</p> <p>3 Q. Are you listed as an author on those</p> <p>4 peer-reviewed publications?</p> <p>5 A. Either an author or as a cite for part of the</p> <p>6 study.</p> <p>7 Q. Which ones do you think in your CV those would</p> <p>8 be?</p> <p>9 A. The study of the third one, the transdermal</p> <p>10 estradiol, that was published in one of the menopausal</p> <p>11 journals, I think. The next one also, as was the third.</p> <p>12 The feminine hygiene study was published. A Double</p> <p>13 Blind Evaluation of Transdermal Estradiol. The third</p> <p>14 from the bottom one was. It was a testosterone study.</p> <p>15 I think those were the only ones that were in peer</p> <p>16 reviews.</p> <p>17 Q. As you sit here today, do you know if you were</p> <p>18 listed as an author in any of those peer-reviewed</p> <p>19 publications?</p> <p>20 A. I was not. Just a cite.</p> <p>21 Q. You were just an investigator at the --</p> <p>22 A. The cite, correct.</p> <p>23 Q. So you've never published as an author in any</p> <p>24 peer-reviewed journal; is that correct?</p>	<p style="text-align: right;">Page 33</p> <p>1 involved with. They were transdermal studies. They did</p> <p>2 dermatologic studies. We did some tampon studies.</p> <p>3 Those types of things.</p> <p>4 Q. When you did those studies as an investigator,</p> <p>5 who compensated you, if anyone, for your work?</p> <p>6 A. Hilltop.</p> <p>7 Q. And that was part of your consultancy with</p> <p>8 Hilltop?</p> <p>9 A. That's correct.</p> <p>10 Q. Why did that stop?</p> <p>11 A. They closed down, or I think they got bought</p> <p>12 out.</p> <p>13 Q. Would it be fair to say that of the research</p> <p>14 and publications we were just looking at, that most of</p> <p>15 those were through Hilltop?</p> <p>16 A. That's correct.</p> <p>17 Q. Were all of those through Hilltop?</p> <p>18 A. I would say the ones that got published, yes.</p> <p>19 Q. How were you compensated by Hilltop?</p> <p>20 A. An hourly wage.</p> <p>21 Q. How much was that hourly wage?</p> <p>22 A. You're testing my memory. I think it was in</p> <p>23 the neighborhood of \$100 an hour, \$125 an hour.</p> <p>24 Q. How did you choose which studies to get</p>

<p style="text-align: right;">Page 34</p> <p>1 involved in with Hilltop?</p> <p>2 A. They would ask me.</p> <p>3 Q. They would come to you and say, "We have a</p> <p>4 study on such and so. Would you like to participate?"</p> <p>5 A. That's correct.</p> <p>6 Q. Just under that in the "Employment" section,</p> <p>7 it says, "1999 to present. Consultant Ethicon Women's</p> <p>8 Health and Urology Speaker and Preceptor."</p> <p>9 A. Right, so it was probably started earlier than</p> <p>10 what I thought.</p> <p>11 Q. You think maybe it goes back to 1999?</p> <p>12 A. Correct.</p> <p>13 Q. It says to present being in 2016.</p> <p>14 A. It hasn't been that long, because they've</p> <p>15 stopped doing them.</p> <p>16 Q. Do you know why Ethicon stopped doing them?</p> <p>17 MR. DIPOLA: Objection to form.</p> <p>18 A. I would assume it's because of all the legal</p> <p>19 issues that they're dealing with.</p> <p>20 Q. So if this is accurate that you were employed</p> <p>21 by Ethicon as early as 1999, do you believe you should</p> <p>22 have contracts from back then as well?</p> <p>23 MR. DIPOLA: Object to form.</p> <p>24 A. I doubt if I have contracts back then.</p>	<p style="text-align: right;">Page 36</p> <p>1 Q. So when it says here in your resume "primary</p> <p>2 investigator," you were not actually a primary</p> <p>3 investigator?</p> <p>4 A. I was not actually a primary investigator.</p> <p>5 Q. You were a consultant on that?</p> <p>6 A. Correct.</p> <p>7 Q. Were you compensated by Ethicon Gynecare for</p> <p>8 your work on that presentation?</p> <p>9 A. I was compensated to go to the meeting and</p> <p>10 present, yes.</p> <p>11 Q. Your resume says under "Employment," from 1999</p> <p>12 to 2003 you were a consultant for Procter &amp; Gamble.</p> <p>13 A. That's correct.</p> <p>14 Q. What was that related to?</p> <p>15 A. They had an osteoporosis drug called Actonel,</p> <p>16 and I was a consultant and would be on their speaker</p> <p>17 program to talk to physicians, gynecologists that deal</p> <p>18 with osteoporosis and the indications and use for</p> <p>19 Actonel in that situation.</p> <p>20 Q. Were you compensated by Procter &amp; Gamble for</p> <p>21 your work on behalf of them for Actonel?</p> <p>22 A. Yes.</p> <p>23 Q. Do you have a sense of how much you were</p> <p>24 compensated over the years for that?</p>
<p style="text-align: right;">Page 35</p> <p>1 Q. Well, back --</p> <p>2 A. Yes. Were they issued? I had contracts, yes.</p> <p>3 Q. You would have been working with Ethicon,</p> <p>4 being compensated by Ethicon, under a contract as early</p> <p>5 as 1999, correct?</p> <p>6 A. Yes.</p> <p>7 Q. But you think it's unlikely you still have</p> <p>8 copies of those contracts?</p> <p>9 A. That's correct.</p> <p>10 Q. But you may have copies of the contracts in</p> <p>11 the later years, 2010, 2011?</p> <p>12 A. Possibly.</p> <p>13 Q. One of the studies that you list as a primary</p> <p>14 investigator on page 5 of your resume is "Clinical</p> <p>15 Evaluation of Gynecare Thermachoice III Uterine Balloon</p> <p>16 System;" is that right?</p> <p>17 A. Yes.</p> <p>18 Q. Was that a Hilltop Research project?</p> <p>19 A. No. That was an Ethicon product, but I did</p> <p>20 not actually perform. I was a consultant on that, and I</p> <p>21 was listed as the investigator, and we presented that at</p> <p>22 one of the AAGL meetings in San Francisco, and so I was</p> <p>23 asked to discuss the study at the presentation. It was</p> <p>24 a poster presentation.</p>	<p style="text-align: right;">Page 37</p> <p>1 A. It wouldn't be very much. Something in the</p> <p>2 neighborhood of maybe three to four thousand dollars.</p> <p>3 Q. Over the four-year period?</p> <p>4 A. Yes.</p> <p>5 Q. It lists from 2002 to 2004 that you were a</p> <p>6 consultant for Organon Pharmaceuticals. What was that</p> <p>7 for?</p> <p>8 A. That was an oral contraceptive pill.</p> <p>9 Q. Which pill?</p> <p>10 A. It was called -- I can't think of it now. It</p> <p>11 was a typical oral contraceptive pill, but I can't think</p> <p>12 of the name of it.</p> <p>13 Q. What was your job for Organon?</p> <p>14 A. I gave a talk on the pill once.</p> <p>15 Q. Did you have some special knowledge or</p> <p>16 experience with that pill?</p> <p>17 A. No.</p> <p>18 Q. Why were you giving the talk?</p> <p>19 A. Because I was a fairly busy</p> <p>20 obstetrician-gynecologist who took care of a lot of</p> <p>21 women and dealt with a lot of contraceptive issues and</p> <p>22 used many different types of contraceptive methods.</p> <p>23 Q. It also says that from '03 to 2004, you were a</p> <p>24 consultant for Pfizer Pharmaceuticals; is that right?</p>

<p style="text-align: right;">Page 38</p> <p>1 A. That's correct.</p> <p>2 Q. What did you do for Pfizer?</p> <p>3 A. They had Premarin cream, which is an estrogen</p> <p>4 cream, and I gave a talk on using estrogen cream for</p> <p>5 post-menopausal atrophic vaginitis.</p> <p>6 Q. Was that, again, just one talk?</p> <p>7 A. One or two.</p> <p>8 Q. Were you compensated by Pfizer for your time</p> <p>9 and work on that product?</p> <p>10 A. Yes.</p> <p>11 Q. You were also a consultant from 2003 until</p> <p>12 present for Cytec Corporation, C-y-t-e-c?</p> <p>13 A. That's correct.</p> <p>14 Q. What is Cytec Corporation?</p> <p>15 A. Cytec was a company that had, again, some</p> <p>16 contraceptives, as well as some hormone replacement</p> <p>17 therapies.</p> <p>18 Q. What did you do for Cytec?</p> <p>19 A. Gave a talk on their product.</p> <p>20 Q. One or more talks?</p> <p>21 A. One.</p> <p>22 Q. Were you compensated by Cytec for your time?</p> <p>23 A. Yes.</p> <p>24 Q. You were a consultant in 2004 to 2003 for Eli</p>	<p style="text-align: right;">Page 40</p> <p>1 consultant?</p> <p>2 MR. DIPOLA: Object to form.</p> <p>3 A. I was sought out, and it worked into my</p> <p>4 schedule.</p> <p>5 Q. Why subsequent to that time period did you not</p> <p>6 continue to consult for Organon, Pfizer, Cytec, or Eli</p> <p>7 Lilly?</p> <p>8 A. Most of the pharmaceutical companies either</p> <p>9 got bought out or merged with other companies, or they</p> <p>10 stopped doing programs.</p> <p>11 Q. 2004 to present, you list yourself as a</p> <p>12 medical advisory board member for Procter &amp; Gamble,</p> <p>13 correct?</p> <p>14 A. Correct.</p> <p>15 Q. Is that true as of today?</p> <p>16 A. No.</p> <p>17 Q. When did that end?</p> <p>18 A. That ended when they sold their pharmaceutical</p> <p>19 division. I'm not sure when that was, but it was</p> <p>20 probably six or seven years ago.</p> <p>21 Q. So maybe sometime around 2010ish?</p> <p>22 A. Maybe.</p> <p>23 Q. You said, Doctor, when we first met this</p> <p>24 morning that you had updated your resume about three</p>
<p style="text-align: right;">Page 39</p> <p>1 Lilly as well?</p> <p>2 A. That's correct.</p> <p>3 Q. What did you do for Eli Lilly?</p> <p>4 A. Spoke on Evista.</p> <p>5 Q. Evista?</p> <p>6 A. Evista.</p> <p>7 Q. How is that spelled?</p> <p>8 A. E-v-i-s-t-a.</p> <p>9 Q. And what --</p> <p>10 A. That's a medication for osteoporosis.</p> <p>11 Q. Is that still on the market?</p> <p>12 A. Yes.</p> <p>13 Q. What was your role for Eli Lilly? You had a</p> <p>14 speaking engagement?</p> <p>15 A. Correct.</p> <p>16 Q. Just one?</p> <p>17 A. I think just one, yes.</p> <p>18 Q. So between 2002 and 2004, you have a number of</p> <p>19 consultancy engagements with six --</p> <p>20 MR. DIPOLA: Object to form.</p> <p>21 Q. -- or so pharmaceutical or medical device</p> <p>22 companies, correct?</p> <p>23 A. Correct.</p> <p>24 Q. Why in that time frame were you so busy as a</p>	<p style="text-align: right;">Page 41</p> <p>1 months ago; is that right?</p> <p>2 A. Yes.</p> <p>3 Q. These are just oversights, I assume?</p> <p>4 A. These are oversights.</p> <p>5 Q. What did you do as a medical advisory board</p> <p>6 member for Procter &amp; Gamble?</p> <p>7 A. Talk about Actonel and meet with people and</p> <p>8 discuss marketing for Actonel.</p> <p>9 Q. What do you mean by "discuss marketing for</p> <p>10 Actonel"?</p> <p>11 A. We would meet, and they would basically have a</p> <p>12 group of doctors in the room, and we would talk about</p> <p>13 osteoporosis and the issues with osteoporosis and the</p> <p>14 competition, the different medications that are out</p> <p>15 there, and what they felt or what -- we would give them</p> <p>16 our opinion as to what we felt would be the right way to</p> <p>17 market the product to the patient that had that problem.</p> <p>18 Q. So part of your role as a member of the</p> <p>19 medical advisory board for Procter &amp; Gamble was to help</p> <p>20 Procter &amp; Gamble understand its target market, correct?</p> <p>21 A. No.</p> <p>22 MR. DIPOLA: Object to form.</p> <p>23 A. To understand what patients would ask or what</p> <p>24 patients verbalize when they talk about osteoporosis</p>

<p style="text-align: right;">Page 42</p> <p>1 with their physician.</p> <p>2 Q. So part of your role was then to help</p> <p>3 Procter &amp; Gamble market Actonel to the correct</p> <p>4 population?</p> <p>5 MR. DIPOLA: Object to form.</p> <p>6 A. No. To help them understand what patients ask</p> <p>7 and discuss with their physicians when they either have</p> <p>8 osteoporosis or they're at high risk for osteoporosis.</p> <p>9 We did not help them market that. We just gave them</p> <p>10 medical information.</p> <p>11 Q. You described it as you discussed marketing</p> <p>12 for Actonel, so I'm just trying to understand what you</p> <p>13 mean by the marketing for Actonel.</p> <p>14 A. We gave them that medical information. What</p> <p>15 they did with it was up to them.</p> <p>16 Q. Did you have a similar role with Eli Lilly</p> <p>17 where you would help them try to understand the market?</p> <p>18 MR. DIPOLA: Object to form.</p> <p>19 A. No.</p> <p>20 Q. On the next item, it says, "2005 to present,</p> <p>21 Consultant, Speaker, and Preceptor for Ethicon Women's</p> <p>22 Health and Urology," correct?</p> <p>23 A. That's correct.</p> <p>24 Q. How is that different from what we were</p>	<p style="text-align: right;">Page 44</p> <p>1 employment as a consultant, speaker, and preceptor for</p> <p>2 American Medical Systems, correct?</p> <p>3 A. That's correct.</p> <p>4 Q. What was your work with AMS?</p> <p>5 A. It was exactly the same. It was professional</p> <p>6 education and preceptorships.</p> <p>7 Q. For which products did you do that for AMS?</p> <p>8 A. Apogee, Perigee, Monarc, MiniArc,</p> <p>9 Anterior/Posterior Elevate, RetroArc, SPARC. I think</p> <p>10 that's it.</p> <p>11 Q. It says that you did this from 2006 to the</p> <p>12 present. Are those dates accurate?</p> <p>13 A. Well, not present. Again, they stopped as</p> <p>14 well.</p> <p>15 Q. Your work for AMS related to mesh products.</p> <p>16 Were you compensated for that work in a similar fashion</p> <p>17 as your work with Ethicon?</p> <p>18 A. Yes.</p> <p>19 MR. DIPOLA: Object to form.</p> <p>20 Q. Did you have contracts, annual contracts, with</p> <p>21 AMS?</p> <p>22 A. Yes.</p> <p>23 Q. Would you say that you did more or less work</p> <p>24 with AMS than you did with Ethicon?</p>
<p style="text-align: right;">Page 43</p> <p>1 reviewing earlier, which was "1999 to present,</p> <p>2 Consultant for Ethicon Women's Health and Urology," if</p> <p>3 it is?</p> <p>4 A. Earlier usually it just meant that Ethicon may</p> <p>5 send some surgeons in to watch me operate, and that was</p> <p>6 all. Then as -- the "Consultant, Speaker," that was</p> <p>7 more prof ed, and preceptorships when I went to</p> <p>8 preceptor people.</p> <p>9 Q. And so --</p> <p>10 A. Whereas, earlier it was just they would come</p> <p>11 watch me in the OR.</p> <p>12 Q. So you think the distinction would be from</p> <p>13 2005 to present, that that was more professional</p> <p>14 education and your traveling to do preceptorships?</p> <p>15 MR. DIPOLA: Object to form.</p> <p>16 A. Yes.</p> <p>17 Q. Again, that says "to present," but is that not</p> <p>18 accurate?</p> <p>19 A. That's not accurate.</p> <p>20 Q. Is that also something that you think ended in</p> <p>21 about 2011, 2012?</p> <p>22 A. I think the last -- maybe the last program I</p> <p>23 gave was 2010 or 2011, yes.</p> <p>24 Q. The next line down, it discusses your</p>	<p style="text-align: right;">Page 45</p> <p>1 MR. DIPOLA: Object to form.</p> <p>2 A. I'd say about equal.</p> <p>3 Q. About equal?</p> <p>4 A. Um-hmm.</p> <p>5 Q. Are there any other consultancies,</p> <p>6 preceptorships, or work that you've done with a</p> <p>7 pharmaceutical company or a medical device company that</p> <p>8 aren't on your resume?</p> <p>9 A. Actually, Cytec now is Hologic, H-o-l-o-g-i-c.</p> <p>10 So that would be the old Cytec-Hologic, but they are</p> <p>11 still the same. So that would be in the same realm.</p> <p>12 And to answer your question, no, I don't think there's</p> <p>13 any other consulting agreements that I'm involved with</p> <p>14 right now that is not listed here.</p> <p>15 Q. Or have been involved with over your career?</p> <p>16 A. Correct.</p> <p>17 Q. Have you ever had your deposition taken</p> <p>18 before?</p> <p>19 A. Yes.</p> <p>20 Q. How many times?</p> <p>21 A. Four.</p> <p>22 Q. Can you briefly describe each of those.</p> <p>23 A. Sure. The first one was as a resident. It</p> <p>24 was -- I was a second year resident in obstetrics and</p>



<p style="text-align: right;">Page 46</p> <p>1 gynecology. It was involving an obstetrics case where a</p> <p>2 lady had a vasa previa, and her baby had some</p> <p>3 complications, and I was the resident involved in the</p> <p>4 delivery of the baby, and it was a lawsuit related to</p> <p>5 that case.</p> <p>6 Q. Was it a medical malpractice lawsuit?</p> <p>7 A. Yes.</p> <p>8 Q. And you were a named defendant?</p> <p>9 A. No. I was just a resident. I wasn't named in</p> <p>10 the case.</p> <p>11 Q. What was the outcome of that case?</p> <p>12 A. The baby had some neurologic issues.</p> <p>13 Q. Do you know what the legal outcome was?</p> <p>14 A. I think it was settled for an amount of money.</p> <p>15 Q. Was your care alleged to be substandard in</p> <p>16 that case?</p> <p>17 MR. DIPOLA: Object to form.</p> <p>18 A. No.</p> <p>19 Q. What about the second?</p> <p>20 A. The second one was I was involved in a</p> <p>21 delivery of a baby that had a brachial plexus injury.</p> <p>22 Q. So that was a medical malpractice case?</p> <p>23 A. Correct.</p> <p>24 Q. Were you a defendant in that case?</p>	<p style="text-align: right;">Page 48</p> <p>1 A. I was deposed as an expert witness in a case</p> <p>2 in Wyoming.</p> <p>3 Q. What type of case?</p> <p>4 A. It was a bowel injury at the time of a vaginal</p> <p>5 hysterectomy.</p> <p>6 Q. On whose behalf were you an expert?</p> <p>7 A. I was an expert on the defense.</p> <p>8 Q. When was that?</p> <p>9 A. 2012, I think. I'm not quite sure.</p> <p>10 Q. Who hired you for that work?</p> <p>11 A. A law firm in Cheyenne, Wyoming.</p> <p>12 Q. Do you know the name of the firm?</p> <p>13 A. I don't know that offhand.</p> <p>14 Q. Do you know the name of the plaintiff in that</p> <p>15 case?</p> <p>16 A. I don't remember.</p> <p>17 Q. Do you know what the outcome was?</p> <p>18 A. Yes.</p> <p>19 Q. What was the outcome?</p> <p>20 A. It was a defense verdict.</p> <p>21 Q. That went to trial, that case?</p> <p>22 A. Yes.</p> <p>23 Q. Did you testify at trial?</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 47</p> <p>1 A. Yes.</p> <p>2 Q. When was that?</p> <p>3 A. 2010.</p> <p>4 Q. Is that case still ongoing?</p> <p>5 A. No.</p> <p>6 Q. You were deposed in that case?</p> <p>7 A. Yes.</p> <p>8 Q. What was the outcome of that case?</p> <p>9 A. That went to trial, and it was a defense</p> <p>10 verdict -- or a plaintiff's verdict. I'm sorry.</p> <p>11 Q. Where did that trial occur?</p> <p>12 A. Cincinnati.</p> <p>13 Q. Do you know what the verdict amount was?</p> <p>14 A. 800,000.</p> <p>15 Q. Do you know who the attorney for the plaintiff</p> <p>16 was?</p> <p>17 A. John Holschuh, I think, is his name.</p> <p>18 Q. What was the plaintiff's name?</p> <p>19 A. Caminiti.</p> <p>20 Q. I'm sorry?</p> <p>21 A. Caminiti.</p> <p>22 Q. Caminiti?</p> <p>23 A. Is her last name, yes.</p> <p>24 Q. What was your third deposition?</p>	<p style="text-align: right;">Page 49</p> <p>1 Q. Do you know if that was in a federal court or</p> <p>2 state court?</p> <p>3 A. I would assume state. I don't know.</p> <p>4 Q. Did you issue a report in that case?</p> <p>5 A. A written report like this (indicating)?</p> <p>6 Q. Yes.</p> <p>7 A. No.</p> <p>8 Q. But you were deposed?</p> <p>9 A. I was deposed here in Cincinnati.</p> <p>10 Q. And also gave trial testimony?</p> <p>11 A. Correct.</p> <p>12 Q. Do you think that trial was in 2012?</p> <p>13 A. I'm trying to think where it was in</p> <p>14 relationship to the brachial plexus. It was after 2010.</p> <p>15 I don't know the exact date.</p> <p>16 Q. What was the fourth deposition?</p> <p>17 A. This one.</p> <p>18 Q. In the Wyoming trial in approximately 2012,</p> <p>19 you were an expert witness; is that right?</p> <p>20 A. That's correct.</p> <p>21 Q. And that was for the defense in that case?</p> <p>22 A. Yes.</p> <p>23 Q. Was that a medical doctor that you were</p> <p>24 testifying on behalf of?</p>

<p style="text-align: right;">Page 50</p> <p>1 A. Yes.</p> <p>2 Q. Other than that Wyoming case and this work</p> <p>3 that we're discussing today and tomorrow, have you done</p> <p>4 any other expert witness work?</p> <p>5 A. I've reviewed cases, yes.</p> <p>6 Q. Have you ever written a report as an expert</p> <p>7 witness other than the report we're looking at today?</p> <p>8 A. No.</p> <p>9 Q. How often would you say that you in the past</p> <p>10 year have looked at cases as you described it as an</p> <p>11 expert?</p> <p>12 MR. DIPAOLA: Object to form.</p> <p>13 A. I looked at a case two or three months ago,</p> <p>14 and this would be -- what we're doing now would be the</p> <p>15 second case this year.</p> <p>16 Q. In prior years, was it something that you did</p> <p>17 a lot of work on?</p> <p>18 A. Not a lot.</p> <p>19 Q. You don't hold yourself out as an expert</p> <p>20 witness in FDA regulations related to medical devices,</p> <p>21 do you?</p> <p>22 A. No.</p> <p>23 Q. You don't hold yourself out as an expert</p> <p>24 witness in marketing of medical devices, do you?</p>	<p style="text-align: right;">Page 52</p> <p>1 A. No.</p> <p>2 Q. Would you consider yourself an expert in</p> <p>3 statistics?</p> <p>4 A. Far from it.</p> <p>5 Q. Would you consider yourself an expert in</p> <p>6 epidemiology?</p> <p>7 A. No.</p> <p>8 Q. What would you consider to be Level 1</p> <p>9 evidence?</p> <p>10 A. That would be a strong meta-analysis,</p> <p>11 randomized control trials. Those would be probably the</p> <p>12 two strongest Level 1 evidence.</p> <p>13 Q. You believe a meta-analysis to be Level 1</p> <p>14 evidence, correct?</p> <p>15 A. If you look at a number of studies, yes.</p> <p>16 Q. What do you mean?</p> <p>17 A. I mean, if you look at a large number of</p> <p>18 studies on the same subject and you analyze them, yes.</p> <p>19 Q. Does it matter if the studies that are</p> <p>20 included in the meta-analysis are observational studies</p> <p>21 or randomized control studies?</p> <p>22 MR. DIPAOLA: Object to form.</p> <p>23 A. Randomized controls would be stronger.</p> <p>24 Q. Do you believe a meta-analysis of</p>
<p style="text-align: right;">Page 51</p> <p>1 A. No.</p> <p>2 Q. You're not an expert in biomaterials; is that</p> <p>3 correct?</p> <p>4 A. No, that's correct.</p> <p>5 Q. You're not an expert in pathology?</p> <p>6 A. I would consider myself not an expert in</p> <p>7 pathology.</p> <p>8 Q. Would you consider yourself an expert in</p> <p>9 drafting instructions for use or IFUs?</p> <p>10 MR. DIPAOLA: Object to form.</p> <p>11 A. No.</p> <p>12 Q. Would you consider yourself or hold yourself</p> <p>13 out as an expert in medical device industry practices?</p> <p>14 MR. DIPAOLA: Object to form.</p> <p>15 A. Could you elaborate on that question?</p> <p>16 Q. Sure. Would you consider yourself or hold</p> <p>17 yourself out as an expert in the development of medical</p> <p>18 devices?</p> <p>19 A. No.</p> <p>20 Q. Would you consider yourself an expert in</p> <p>21 design of medical devices?</p> <p>22 MR. DIPAOLA: Object to form.</p> <p>23 A. No.</p> <p>24 Q. Have you ever designed a clinical study?</p>	<p style="text-align: right;">Page 53</p> <p>1 observational studies is equivalent level of evidence to</p> <p>2 a randomized control trial?</p> <p>3 A. No.</p> <p>4 Q. Which is stronger?</p> <p>5 A. The randomized control trial.</p> <p>6 Q. Do you understand or have an appreciation of</p> <p>7 the difference between a relative risk and an odds</p> <p>8 ratio?</p> <p>9 MR. DIPAOLA: Object to form.</p> <p>10 A. Somewhat.</p> <p>11 Q. What is the difference?</p> <p>12 A. Relative risk, it gives you the chance of</p> <p>13 developing a problem when you're looking at two</p> <p>14 statistics or two varying techniques or procedures. And</p> <p>15 odds ratio is what your chances of developing a problem</p> <p>16 is in relationship to whatever problem you're looking</p> <p>17 at.</p> <p>18 Q. What did you do to prepare for today's</p> <p>19 deposition?</p> <p>20 A. Reviewed the records of the patients that</p> <p>21 we're going to be talking about tomorrow. Reviewed my</p> <p>22 report. Obviously did not update my CV correctly.</p> <p>23 Looked at some information that was provided by Butler</p> <p>24 Snow. Reviewed some articles that I've looked at in the</p>



<p style="text-align: right;">Page 54</p> <p>1 past. Maybe read some abstracts on some of those</p> <p>2 articles, textbooks that I used when I prepared my</p> <p>3 report. That's really it.</p> <p>4 Q. Did you meet with counsel for Ethicon?</p> <p>5 A. With Ethicon?</p> <p>6 Q. Yes.</p> <p>7 A. Would that be Doug?</p> <p>8 Q. Yes.</p> <p>9 A. Yes.</p> <p>10 Q. Did you meet with any other attorneys other</p> <p>11 than Doug?</p> <p>12 A. No.</p> <p>13 Q. When did you meet with Ethicon's counsel?</p> <p>14 MR. DIPAOLA: Object to form.</p> <p>15 A. We met last Tuesday.</p> <p>16 Q. And for how long?</p> <p>17 A. About three hours.</p> <p>18 Q. And before last Tuesday -- is that the last</p> <p>19 time you met with him other than this morning?</p> <p>20 A. Correct.</p> <p>21 Q. Prior to that, had you met with him in person</p> <p>22 before or by phone?</p> <p>23 A. Yes.</p> <p>24 Q. When?</p>	<p style="text-align: right;">Page 56</p> <p>1 of vaginal hysterectomy in minimally invasive surgery</p> <p>2 and pelvic floor surgery.</p> <p>3 Q. Did that include discussions about mesh?</p> <p>4 A. No.</p> <p>5 Q. We discussed earlier a number of depositions</p> <p>6 and trial testimony that you've given. Do you recall</p> <p>7 that?</p> <p>8 A. Yes.</p> <p>9 Q. Other than the brachial plexus case, have you</p> <p>10 ever been sued in any way?</p> <p>11 A. No.</p> <p>12 Q. In your expert report, you say you've</p> <p>13 performed over 2,000 slings.</p> <p>14 A. That's correct.</p> <p>15 Q. Is that from 1999 until present?</p> <p>16 A. Yes.</p> <p>17 Q. Do you have a sense of the breakdown in your</p> <p>18 practice over time of which slings you used over the</p> <p>19 years?</p> <p>20 A. You mean specific slings or types of slings?</p> <p>21 The main types of slings are retropubic slings and</p> <p>22 transobturator slings. And I would say through my</p> <p>23 career, I've probably done maybe 65 to 70 percent</p> <p>24 transobturator slings, and the other 20, 25 percent</p>
<p style="text-align: right;">Page 55</p> <p>1 A. By phone, I can't tell you exactly when, but</p> <p>2 we've had phone conversations, and the first time I met</p> <p>3 Doug was at my office, and that was about two years ago</p> <p>4 when we were looking at -- I think when we were looking</p> <p>5 at reviewing some cases.</p> <p>6 Q. Is that the first time you were approached to</p> <p>7 work on Ethicon mesh cases, about two years ago?</p> <p>8 A. Yes.</p> <p>9 Q. And it was Doug that met you?</p> <p>10 A. Correct.</p> <p>11 (Short recess taken.)</p> <p>12 Q. Doctor, on Exhibit 2, which is a copy of your</p> <p>13 report, you have there "Education, Training and</p> <p>14 Experience" on the first page. Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. It says 2013 and 2015, down at the bottom</p> <p>17 there. You were a presenter at an AUGS meeting, A-U-G-S</p> <p>18 meeting; is that correct?</p> <p>19 A. Yes.</p> <p>20 Q. Do you know what those two presentations were?</p> <p>21 A. Yes. The first one was on -- I'm trying to</p> <p>22 think what we presented on. It was a round table</p> <p>23 discussion on -- oh, the 2015 was a -- both of them were</p> <p>24 round table discussions on the indication for or the use</p>	<p style="text-align: right;">Page 57</p> <p>1 would be retropubic.</p> <p>2 Q. And you use both AMS and Ethicon's products,</p> <p>3 correct?</p> <p>4 A. I do, yes.</p> <p>5 Q. Is that current today? You still use both?</p> <p>6 A. Actually, AMS is taking their products off the</p> <p>7 market. But, yes, as of, I think, March 31st, they</p> <p>8 still have product on the shelf.</p> <p>9 Q. Did you have a particular percentage of use of</p> <p>10 AMS versus Ethicon products?</p> <p>11 MR. DIPAOLA: Object to form.</p> <p>12 A. I can't really give you a percentage. It's</p> <p>13 more patient specific.</p> <p>14 Q. Other than AMS and Ethicon slings, have you</p> <p>15 used any other slings?</p> <p>16 A. I've tried a few, but I've never used any</p> <p>17 on -- more than those on a regular basis.</p> <p>18 Q. Why did you choose to use Ethicon and AMS</p> <p>19 slings?</p> <p>20 A. Ethicon slings I chose to use because they</p> <p>21 were the first slings that came out, in my experience.</p> <p>22 And in looking at the data that they had behind their</p> <p>23 slings, I felt that it was the sling that had the best</p> <p>24 data out there, and so that's why I continue to use</p>

<p style="text-align: right;">Page 58</p> <p>1 those slings.</p> <p>2 Q. Why do you use AMS slings?</p> <p>3 A. AMS makes a -- or did make a single-incision</p> <p>4 sling called MiniArc; and of the single-incision slings,</p> <p>5 MiniArc in my hands seemed to work the best, and in my</p> <p>6 patient population seemed to give me the best results.</p> <p>7 So I use that.</p> <p>8 There's a certain subset of population that</p> <p>9 I'm doing a transobturator approach on; and in that</p> <p>10 situation, under certain circumstances, I'll use an</p> <p>11 outside-in transobturator, which is their Monarc, versus</p> <p>12 an inside-out. And I use their SPARC, which is a</p> <p>13 top-down retropubic.</p> <p>14 Q. Would you say you have a particular preference</p> <p>15 for the SPARC as compared to the TVT?</p> <p>16 MR. DIPAOLO: Object to form.</p> <p>17 A. My go-to retropubic sling is a TVT Exact</p> <p>18 today.</p> <p>19 Q. What is your go-to obturator sling today?</p> <p>20 A. It's equal between a Monarc and TVT Abbrevo.</p> <p>21 Q. What informs your choice of whether to use the</p> <p>22 Monarc or the Abbrevo?</p> <p>23 MR. DIPAOLO: Object to form.</p> <p>24 A. It has to do with the type of incontinence</p>	<p style="text-align: right;">Page 60</p> <p>1 Q. When was the last time you think you did a</p> <p>2 Burch?</p> <p>3 A. 2000 something, in the early 2000s, I'd say.</p> <p>4 Q. You would agree that the Burch today is a safe</p> <p>5 and effective procedure, correct?</p> <p>6 MR. DIPAOLO: Object to form.</p> <p>7 A. Yes.</p> <p>8 Q. What is in your decision-making process when</p> <p>9 you're choosing whether to do a retropubic or an</p> <p>10 obturator procedure?</p> <p>11 A. I'll use an obturator procedure for somebody</p> <p>12 that I would consider a simple, if there is such a</p> <p>13 thing, hypermobile urethra that does not have intrinsic</p> <p>14 sphincter deficiency, has not failed a previous surgery.</p> <p>15 That would be an obturator.</p> <p>16 Q. So for an ISD patient, you would not choose an</p> <p>17 obturator approach; is that correct?</p> <p>18 A. In the majority of cases.</p> <p>19 Q. Or for a patient who has a more complex</p> <p>20 presentation, you would not necessarily choose an</p> <p>21 obturator approach?</p> <p>22 MR. DIPAOLO: Object to form.</p> <p>23 A. Not so much complex as the situation.</p> <p>24 Q. What do you mean by that?</p>
<p style="text-align: right;">Page 59</p> <p>1 they have, the weight of the patient, if they've had</p> <p>2 previous surgeries or not, the anatomy of the obturator</p> <p>3 space. Those are probably the four biggest.</p> <p>4 Q. Are there any other surgical procedures that</p> <p>5 you've used to treat stress urinary incontinence apart</p> <p>6 from the TVT and AMS products?</p> <p>7 A. Today or in my past?</p> <p>8 Q. Let's start with today.</p> <p>9 A. Today, that, and there's a rare occasion where</p> <p>10 we'll use a -- or I will use a pubofascial sling.</p> <p>11 Q. What would that rare occasion be today?</p> <p>12 A. In a patient who absolutely does not want to</p> <p>13 have a mesh product, in a patient who has had multiple</p> <p>14 mesh slings and failed, in somebody who has a very rigid</p> <p>15 urethra and so we need to do something more at the</p> <p>16 bladder neck than at the midurethra.</p> <p>17 Q. How often would you say you've done that type</p> <p>18 of surgery in the past year?</p> <p>19 A. In the past year, I don't think I've done one.</p> <p>20 I think the last one was last year.</p> <p>21 Q. In 1999, prior to your starting to use the TVT</p> <p>22 Retropubic, how were you treating stress urinary</p> <p>23 incontinence in your practice?</p> <p>24 A. Burch.</p>	<p style="text-align: right;">Page 61</p> <p>1 A. Well, if somebody had ISD but they had mixed</p> <p>2 incontinence where they had a very, very significant</p> <p>3 amount of overactive bladder, even though from an</p> <p>4 anatomical standpoint, a retropubic might be the better</p> <p>5 procedure, but you might increase her overactive bladder</p> <p>6 symptoms, so I would probably use a transobturator</p> <p>7 approach and put it in a little tighter.</p> <p>8 Q. You would tension in the tape a little</p> <p>9 tighter?</p> <p>10 A. In that situation, yes.</p> <p>11 Q. Do you believe the TVT is more efficacious for</p> <p>12 intrinsic sphincter deficiency?</p> <p>13 A. I do.</p> <p>14 Q. Do you base that on any scientific literature,</p> <p>15 or is that based on your own experience?</p> <p>16 A. Both.</p> <p>17 Q. If Ethicon was aware that the obturator was</p> <p>18 not as efficacious for treatment of intrinsic sphincter</p> <p>19 deficiency as compared to the retropubic, do you believe</p> <p>20 that's something Ethicon should have informed physicians</p> <p>21 of?</p> <p>22 MR. DIPAOLO: Object to form.</p> <p>23 A. No.</p> <p>24 Q. Doctor, in your report -- I'm sorry. There</p>

<p style="text-align: right;">Page 62</p> <p>1 aren't page numbers on my version.</p> <p>2 A. That's okay.</p> <p>3 Q. But there are a number of diagrams --</p> <p>4 A. Yes.</p> <p>5 Q. -- that start with Kelly plication. Do you</p> <p>6 see that?</p> <p>7 A. Yes.</p> <p>8 Q. Where did you get that diagram?</p> <p>9 A. That was from a -- actually, on the last page,</p> <p>10 all my diagrams are from the Atlas of Pelvic Anatomy and</p> <p>11 Gynecology, Surgery for Urinary Incontinence and from</p> <p>12 the Urogynecology and Reconstructive Surgery book. All</p> <p>13 the diagrams are from those two sites.</p> <p>14 Q. Those are all books written in part by your</p> <p>15 brother; is that right?</p> <p>16 A. The Baggish and Karraam Atlas, yes. The</p> <p>17 urogyn, that was a synopsis of multiple different</p> <p>18 authors. Some of those are his, and some of them are</p> <p>19 from other authors within that textbook.</p> <p>20 Q. The next diagram is for the MMK repair.</p> <p>21 A. Yes.</p> <p>22 Q. Then what is the next diagram?</p> <p>23 A. Hang on a second. So the MMK is</p> <p>24 Marshall-Marchetti-Krantz, and then the next is the</p>	<p style="text-align: right;">Page 64</p> <p>1 A. A fascial sling.</p> <p>2 Q. A fascial sling?</p> <p>3 A. Yes.</p> <p>4 Q. And you say there that the TVT -- the third</p> <p>5 line down, it starts with, "It has the advantages." Do</p> <p>6 you see that sentence?</p> <p>7 A. Yes.</p> <p>8 Q. You say, "The TVT has the advantages of a</p> <p>9 minimally invasive outpatient procedure and results that</p> <p>10 are comparable to the Burch procedure." Do you believe</p> <p>11 that the TVT has results that are comparable to the</p> <p>12 Burch procedure?</p> <p>13 A. Yes.</p> <p>14 Q. Two pages later you have a photo of a</p> <p>15 retropubic TVT.</p> <p>16 A. That's correct.</p> <p>17 Q. And then after that, you say "(also showing</p> <p>18 the loose tensioning technique)." Is that right?</p> <p>19 A. Yes.</p> <p>20 Q. What do you mean by "loose tensioning</p> <p>21 technique"?</p> <p>22 MR. DIPOLA: Object to form.</p> <p>23 A. To leave the sling under the urethra very</p> <p>24 loosely and leave a space in between the urethra and the</p>
<p style="text-align: right;">Page 63</p> <p>1 Burch. It says, "Photo of a Burch repair."</p> <p>2 Q. That's a Burch repair that you're showing</p> <p>3 there?</p> <p>4 A. Yes.</p> <p>5 Q. Then on the next page is a combined Burch and</p> <p>6 paravaginal repair?</p> <p>7 A. That's correct.</p> <p>8 Q. Have you ever performed that procedure?</p> <p>9 A. Yes.</p> <p>10 Q. When is the last time you think you did that?</p> <p>11 A. Before 2000.</p> <p>12 Q. Then the next one is another picture of a</p> <p>13 Burch repair, correct?</p> <p>14 A. Yes.</p> <p>15 Q. What's the difference between that photo of a</p> <p>16 Burch repair and the one two pages earlier?</p> <p>17 A. Just another photo. There's nothing -- the</p> <p>18 photo -- the first one is tied, and you can see that the</p> <p>19 way the first one is tied, the first photo, it ties</p> <p>20 across the ligament; whereas, in the second photo, you</p> <p>21 actually pass the sutures through and tie on top of the</p> <p>22 ligament, which is the better way to do it.</p> <p>23 Q. You say a few pages later in your report</p> <p>24 there's a picture of a -- a photo of a fascial sling.</p>	<p style="text-align: right;">Page 65</p> <p>1 sling.</p> <p>2 Q. Do you believe that that's how the tensioning</p> <p>3 is described in the IFU?</p> <p>4 MR. DIPOLA: Object to form.</p> <p>5 A. Actually, I'm not sure how it's described in</p> <p>6 the IFU.</p> <p>7 Q. You agree that a complication of -- a</p> <p>8 well-recognized complication with TVT is bladder</p> <p>9 perforation, correct?</p> <p>10 MR. DIPOLA: Objection to form.</p> <p>11 A. Yes.</p> <p>12 Q. You also opine that routine cystoscopy is</p> <p>13 performed on all sling procedures, correct?</p> <p>14 A. Correct.</p> <p>15 Q. Do you think that is a requirement that should</p> <p>16 be done for standard of care on all TVT procedures?</p> <p>17 MR. DIPOLA: Object to form.</p> <p>18 A. In my opinion, yes.</p> <p>19 Q. Do you believe that should be noted as a</p> <p>20 requirement in the instructions for use?</p> <p>21 MR. DIPOLA: Object to form.</p> <p>22 A. No.</p> <p>23 Q. Do you believe that there is a certain</p> <p>24 population of physicians who are using the TVT device</p>

<p style="text-align: right;">Page 66</p> <p>1 who may not be as skilled at cystoscopy?</p> <p>2 MR. DIPOLA: Object to form.</p> <p>3 A. No.</p> <p>4 Q. Doctor, I asked you earlier whether or not you</p> <p>5 had been involved in any other lawsuits other than the</p> <p>6 four that we've discussed. Do you recall that?</p> <p>7 A. Yes.</p> <p>8 Q. You've been involved in one other lawsuit that</p> <p>9 I found as well involving the Department of Justice. Do</p> <p>10 you recall that?</p> <p>11 A. Yes.</p> <p>12 Q. An action was brought against you by the</p> <p>13 United States of America, correct?</p> <p>14 A. Correct.</p> <p>15 Q. And it was for violation of the antitrust act,</p> <p>16 correct?</p> <p>17 A. It was in their opinion, yes.</p> <p>18 Q. The United States of America brought a lawsuit</p> <p>19 against you and a number of other doctors alleging that</p> <p>20 you had conspired with those doctors to inhibit</p> <p>21 competition in the Cincinnati area, correct?</p> <p>22 A. That was their opinion, yes. And just for</p> <p>23 clarification, I thought when you asked me that</p> <p>24 question, you were talking about medical malpractice.</p>	<p style="text-align: right;">Page 68</p> <p>1 States versus Federation of Physicians and Dentists, et</p> <p>2 al.," correct?</p> <p>3 A. Correct.</p> <p>4 Q. This is a lawsuit, if you look at the second</p> <p>5 paragraph, filed on June 24th, 2005, correct?</p> <p>6 A. Correct.</p> <p>7 Q. You were a defendant in this lawsuit, correct?</p> <p>8 A. Correct.</p> <p>9 Q. It says, "On June 24th, 2005, the United</p> <p>10 States filed a complaint alleging that the Federation of</p> <p>11 Physicians and Dentists (Federation), Dr. Michael</p> <p>12 Karram, Dr. Warren Metherd, and Dr. James Wendel</p> <p>13 conspired with other OB-GYN members to increase fees</p> <p>14 paid by commercial insureds to Federation members in</p> <p>15 violation of the Sherman Act Section 1." Did I read</p> <p>16 that correctly?</p> <p>17 A. Yes.</p> <p>18 Q. You reached, along with the other two doctors,</p> <p>19 a settlement with the United States of this antitrust</p> <p>20 case, correct?</p> <p>21 A. That's correct.</p> <p>22 Q. If you look on the second page, the bottom</p> <p>23 left, paragraph 1, "Nature and Purpose of the</p> <p>24 Proceedings." Do you see where I am?</p>
<p style="text-align: right;">Page 67</p> <p>1 Q. Understood. So let me back up and say are</p> <p>2 there any other lawsuits in which you've been involved</p> <p>3 even outside of the medical realm all together?</p> <p>4 A. Not that I'm aware of.</p> <p>5 MR. ZONIES: So we'll go ahead and mark this</p> <p>6 as Exhibit 7.</p> <p>7 - - -</p> <p>8 FEDERAL REGISTER, VOLUME 70, NO.</p> <p>9 147, TUESDAY, AUGUST 2, 2005,</p> <p>10 NOTICES, PAGES 44376-44387 WAS</p> <p>11 MARKED AS EXHIBIT NO. 7.</p> <p>12 - - -</p> <p>13 BY MR. ZONIES:</p> <p>14 Q. We've marked this as Exhibit 7, Doctor.</p> <p>15 A. Okay.</p> <p>16 Q. Doctor, I've handed you a document. You can</p> <p>17 see at the top it's from the Federal Register, and it's</p> <p>18 notices dated August 2nd, 2005; is that right?</p> <p>19 A. Yes.</p> <p>20 Q. If you look at Department of Justice in the</p> <p>21 right-hand column -- do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. And this is the "Antitrust Division Proposed</p> <p>24 Final Judgment and Competitive Impact Statement, United</p>	<p style="text-align: right;">Page 69</p> <p>1 A. Yes.</p> <p>2 Q. And this is in the Federal Register, Volume</p> <p>3 70, No. 147, page 44377; is that right?</p> <p>4 A. Yes.</p> <p>5 Q. It says, "The Plaintiff filed this civil</p> <p>6 antitrust Complaint on June 24th, 2005, in the United</p> <p>7 States District Court for the Southern District of Ohio,</p> <p>8 Western Division, alleging that Drs. Warren Metherd,</p> <p>9 Michael Karram, James Wendel (the Settling Physician</p> <p>10 Defendants), obstetrician-gynecologist physicians,</p> <p>11 (OB-GYNs) practicing in Cincinnati, Ohio, participated</p> <p>12 in a conspiracy that has unreasonably restrained</p> <p>13 interstate trade and commerce in violation of Section 1</p> <p>14 of the Sherman Act." Is that right?</p> <p>15 A. Is that what it says?</p> <p>16 Q. Yes.</p> <p>17 A. Yes.</p> <p>18 Q. That's the complaint brought by -- the</p> <p>19 plaintiff in this case is actually the United States of</p> <p>20 America, correct?</p> <p>21 A. Correct.</p> <p>22 Q. The Department of Justice?</p> <p>23 A. Correct.</p> <p>24 MR. DIPOLA: Objection to relevance and form</p>

<p style="text-align: right;">Page 70</p> <p>1 to this whole line of questioning.</p> <p>2 Q. The document goes on to state, "As alleged in</p> <p>3 the complaint, this agreement has artificially raised</p> <p>4 fees paid by health insurers to OB-GYNs in the</p> <p>5 Cincinnati area that are ultimately borne by employers</p> <p>6 and their employees." That was the allegation in the</p> <p>7 complaint, correct?</p> <p>8 A. Correct.</p> <p>9 Q. And you settled that complaint, correct?</p> <p>10 A. Correct. A consent decree, if that's a</p> <p>11 settlement, yes.</p> <p>12 Q. And under that consent decree, you had a</p> <p>13 continuing obligation for a period of ten years</p> <p>14 following the date of entry of the final judgment to</p> <p>15 certify annually to the United States of America that</p> <p>16 you were complying with the terms of the consent decree,</p> <p>17 correct?</p> <p>18 A. Correct.</p> <p>19 Q. Have you done that for ten years?</p> <p>20 A. And it's over, yes.</p> <p>21 Q. It ended in 2015?</p> <p>22 A. Correct.</p> <p>23 Q. The gist of this complaint was effectively</p> <p>24 that you and other physicians had gotten together in an</p>	<p style="text-align: right;">Page 72</p> <p>1 trying to get better reimbursements?</p> <p>2 A. The letters came from the federation, and we</p> <p>3 met with insurance companies, yes, on an individual</p> <p>4 basis, representing our practices individually, not</p> <p>5 together.</p> <p>6 Q. As part of the allegations in this complaint,</p> <p>7 the United States, the Department of Justice, alleges</p> <p>8 that from December of 2002 through March of 2003, that</p> <p>9 you, Dr. Karram, and Dr. Wendel's large OB-GYN groups</p> <p>10 spearheaded federation member group's attempts to</p> <p>11 renegotiate their contracts with Anthem and Humana,</p> <p>12 correct?</p> <p>13 MR. DIPOLA: Same objection.</p> <p>14 A. That's what they said, but that's not what</p> <p>15 happened.</p> <p>16 Q. The allegation specifically quote emails from</p> <p>17 you to a Ms. Odenkirk. Is she with the federation?</p> <p>18 A. That's correct.</p> <p>19 Q. And one of the quotes is, "I agree with</p> <p>20 Warren. We need to get everyone moving faster and to</p> <p>21 become more persistent; otherwise, they will not get</p> <p>22 increases in 2003. I'm sure that is what ChoiceCare is</p> <p>23 doing."</p> <p>24 MR. DIPOLA: Object. Is there a question?</p>
<p style="text-align: right;">Page 71</p> <p>1 effort to get health insurance companies to provide</p> <p>2 higher reimbursement for procedures that you were</p> <p>3 performing, correct?</p> <p>4 MR. DIPOLA: Object to form.</p> <p>5 A. Incorrect.</p> <p>6 Q. What do you understand this complaint to be,</p> <p>7 the activity that this complaint was addressing?</p> <p>8 A. There was an organization called the</p> <p>9 Federation of Physicians and Surgeons -- or Physicians</p> <p>10 and Dentists. They came into the Cincinnati area to</p> <p>11 recruit physicians to join what they considered a legal</p> <p>12 union. And so all the physicians involved in this case,</p> <p>13 and many of the other practices in the city, joined and</p> <p>14 became members of the federation.</p> <p>15 And so we all thought that we were members of</p> <p>16 the union. And they had their union representatives</p> <p>17 come in here and talk to us about how we can negotiate</p> <p>18 with insurance companies from a legal standpoint based</p> <p>19 on their expertise and utilize them in a legal way based</p> <p>20 on their expertise to help us negotiate better terms for</p> <p>21 our reimbursements.</p> <p>22 Q. And working together as a group with the</p> <p>23 federation, you and these other OB-GYNs in the area</p> <p>24 wrote letters, for example, to the insurance companies</p>	<p style="text-align: right;">Page 73</p> <p>1 MR. ZONIES: I'm reading from the document.</p> <p>2 MR. DIPOLA: Okay.</p> <p>3 BY MR. ZONIES:</p> <p>4 Q. "Just think of the money they will save if</p> <p>5 they keep delaying people until 2004." Is that an email</p> <p>6 that you had written?</p> <p>7 A. I don't recall that.</p> <p>8 Q. Do you deny that that is an email that you</p> <p>9 wrote?</p> <p>10 A. I don't recall that.</p> <p>11 Q. If you look at page 44387, paragraph 76, of</p> <p>12 the complaint that was filed by the Department of</p> <p>13 Justice against you and others.</p> <p>14 A. What was that page, 44,000 --</p> <p>15 Q. 44,387.</p> <p>16 A. 87. Okay.</p> <p>17 Q. Paragraph 76.</p> <p>18 A. 76?</p> <p>19 Q. Yes. Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. The allegation in paragraph 76 by the</p> <p>22 Department of Justice is, "This combination and</p> <p>23 conspiracy has had the following effects, among others,"</p> <p>24 and then it goes on to say in paragraph B, "Healthcare</p>



<p style="text-align: right;">Page 74</p> <p>1 insurance companies in the Cincinnati area and their</p> <p>2 subscribers have been denied the benefits of free and</p> <p>3 open competition in the purchase of OB-GYN services in</p> <p>4 the Cincinnati area." That was the allegation, correct?</p> <p>5 A. That's what it says, yes.</p> <p>6 Q. It goes on to say, "Self-insured employers and</p> <p>7 their employees have paid significantly higher prices</p> <p>8 for OB-GYN services in the Cincinnati area than they</p> <p>9 would have paid in the absence of this restraint of</p> <p>10 trade." That was the allegation, correct?</p> <p>11 A. That's what it says.</p> <p>12 Q. So, for example, some of the services that you</p> <p>13 would have been providing at the time to your patients</p> <p>14 and for which you would be turning for reimbursement</p> <p>15 from Aetna and Humana would be TVT and TVT-O procedures,</p> <p>16 correct?</p> <p>17 A. Correct.</p> <p>18 Q. And these are allegations that through the</p> <p>19 efforts of the federation and you and other physicians</p> <p>20 in the area, that the prices for those procedures were</p> <p>21 artificially enhanced by violating the Sherman Act,</p> <p>22 correct?</p> <p>23 MR. DIPAOLA: Object to form.</p> <p>24 A. No, incorrect. That's not correct.</p>	<p style="text-align: right;">Page 76</p> <p>1 A. Yes.</p> <p>2 Q. Would it be your testimony that you have</p> <p>3 reviewed every single one of these articles either in</p> <p>4 the abstract or in detail?</p> <p>5 MR. DIPAOLA: Object to form.</p> <p>6 A. No.</p> <p>7 Q. This was a list that was provided to you? You</p> <p>8 didn't create this list; is that fair?</p> <p>9 A. Some of the articles, and then some of this I</p> <p>10 did provide, and others were provided to me, and I am</p> <p>11 familiar with quite a few of these in the sense that I</p> <p>12 have read either the articles themselves or abstracts or</p> <p>13 maybe have discussed some at conferences or different</p> <p>14 medical meetings.</p> <p>15 Q. You do cite to some papers in the body of your</p> <p>16 report, correct?</p> <p>17 A. Correct.</p> <p>18 Q. The choices you made on which papers to cite</p> <p>19 in the body of your report, what drove that choice?</p> <p>20 A. The articles that I used to prepare my -- and</p> <p>21 the information that I used to prepare my report.</p> <p>22 Q. Do you somehow consider the ones that you</p> <p>23 cited in the body of your report to be the seminal</p> <p>24 papers on the topics that you cite them for?</p>
<p style="text-align: right;">Page 75</p> <p>1 Q. You don't think that's what the allegations</p> <p>2 were?</p> <p>3 A. No. I think the allegations were that we were</p> <p>4 trying to get reimbursement similar to other parts of</p> <p>5 the country for the procedures that we were</p> <p>6 participating in.</p> <p>7 Q. You were trying to get paid more?</p> <p>8 A. We were trying to get --</p> <p>9 MR. DIPAOLA: Object to form.</p> <p>10 A. -- reimbursed equally across the board just</p> <p>11 like anybody else in the country.</p> <p>12 Q. Had you been involved in any other civil</p> <p>13 actions of any sort involving the United States?</p> <p>14 A. No.</p> <p>15 Q. Have you ever had your medical license in any</p> <p>16 way revoked or put on hold?</p> <p>17 A. No.</p> <p>18 Q. Could you turn, please, to what I'm handing</p> <p>19 you as Exhibit 4, your reliance materials. Do you have</p> <p>20 that in front of you?</p> <p>21 A. Yes.</p> <p>22 Q. Your reliance materials start with a section</p> <p>23 called "Medical Literature" dated 3/2/2016; is that</p> <p>24 right?</p>	<p style="text-align: right;">Page 77</p> <p>1 MR. DIPAOLA: Object to form.</p> <p>2 A. Seminal meaning?</p> <p>3 Q. The key papers on the topics that you're</p> <p>4 citing them for.</p> <p>5 A. Just in my opinion what I looked at, yes.</p> <p>6 Q. What you would choose to back up your opinions</p> <p>7 effectively?</p> <p>8 A. Some of them, yes.</p> <p>9 Q. Did you cite in your report any papers you</p> <p>10 felt didn't support your opinion but you analyzed why</p> <p>11 they wouldn't be applicable?</p> <p>12 MR. DIPAOLA: Object to form.</p> <p>13 A. No.</p> <p>14 Q. In your report, you only cite those papers</p> <p>15 that support your opinion, correct?</p> <p>16 A. Yes, for the most part, yes.</p> <p>17 Q. If you keep on going, the next section is</p> <p>18 called "Production Materials." Do you see that? It's</p> <p>19 just after the last Zyczynski, Z-y-c-z-y-n-s-k-i.</p> <p>20 A. This (indicating)?</p> <p>21 Q. Yes.</p> <p>22 A. Okay.</p> <p>23 Q. Do you see in the top left corner of that, it</p> <p>24 says "Production Materials"?</p>

<p style="text-align: right;">Page 78</p> <p>1 A. Yes.</p> <p>2 Q. All right. And if you look at that page and</p> <p>3 the next page, this is what I was talking about where it</p> <p>4 says ETH.MESH. Do you see a lot of those ETH.MESH?</p> <p>5 A. Yes.</p> <p>6 Q. These are internal Ethicon documents?</p> <p>7 A. Right.</p> <p>8 Q. These documents -- you've already said that</p> <p>9 you haven't reviewed internal documents, correct?</p> <p>10 MR. DIPOLA: Object to form.</p> <p>11 A. That's correct, I have not.</p> <p>12 Q. So you haven't reviewed, for example, an</p> <p>13 email -- if you look at the second page at the top,</p> <p>14 "Email from Dan Smith, re: NG TVT-O NDP. Outcomes from</p> <p>15 kickoff meeting with Professor De Leval and</p> <p>16 Dr. Waltregny, ETH.MESH.2293715-6." You wouldn't have</p> <p>17 reviewed that document, correct?</p> <p>18 A. Correct.</p> <p>19 Q. And you're not relying on that document for</p> <p>20 your opinion, correct?</p> <p>21 A. Correct.</p> <p>22 Q. Would the same be said of all of these</p> <p>23 ETH.MESH documents or the documents that say "Email from</p> <p>24 Hinoul," et cetera?</p>	<p style="text-align: right;">Page 80</p> <p>1 A. Yes.</p> <p>2 Q. It sounds to me, just from reading the title,</p> <p>3 that that might be a prof ed piece.</p> <p>4 A. It could be, yes, and if it was, I probably</p> <p>5 saw it in some form.</p> <p>6 Q. At some point --</p> <p>7 A. Yes.</p> <p>8 Q. -- or in particular for working on your</p> <p>9 opinion?</p> <p>10 A. No. Probably in prof ed when I was giving a</p> <p>11 course or something.</p> <p>12 Q. Understood.</p> <p>13 A. Right.</p> <p>14 Q. But even the prof ed ones that might be listed</p> <p>15 on here, you didn't specifically look at those in</p> <p>16 preparation of your report and rely upon those; is that</p> <p>17 fair?</p> <p>18 A. No.</p> <p>19 MR. DIPOLA: Object to form.</p> <p>20 A. Correct.</p> <p>21 Q. As a matter of fact, have you seen any</p> <p>22 documents where on the bottom right corner of the</p> <p>23 document it says ETH.MESH and there's a number?</p> <p>24 A. No, not that I'm aware of.</p>
<p style="text-align: right;">Page 79</p> <p>1 MR. DIPOLA: Object to form; foundation.</p> <p>2 A. Any email or documents, yes, if there's</p> <p>3 something in here that has to do with a prof ed slide, I</p> <p>4 might have looked at. But other than that, no, I'm not</p> <p>5 familiar with any of this.</p> <p>6 Q. So, for example, if you turn to the next page,</p> <p>7 the sixth one down is entitled "Gynemesh PS Slide Deck</p> <p>8 2004," that may be a prof ed piece, for example?</p> <p>9 A. Correct.</p> <p>10 Q. So that's something you may have reviewed?</p> <p>11 A. Or I may have looked at, yes, or seen.</p> <p>12 Q. Do you know if you actually did look at that?</p> <p>13 MR. DIPOLA: Object to form.</p> <p>14 A. "The Gynecare Gynemesh PS, a new mesh for</p> <p>15 pelvic floor repair," is that what you're looking at</p> <p>16 under "Government Submissions"? I don't know which page</p> <p>17 you're on.</p> <p>18 Q. I'm sorry.</p> <p>19 A. That's all right. That's all right.</p> <p>20 Q. They're not numbered. So if you back up one</p> <p>21 page.</p> <p>22 A. Okay.</p> <p>23 Q. And if you look at the sixth one down, it</p> <p>24 says, "Gynemesh PS Slide Deck 2004." Do you see that?</p>	<p style="text-align: right;">Page 81</p> <p>1 Q. In the preparation of your report, the time</p> <p>2 frame we said was four or five months; is that right?</p> <p>3 A. Maybe more, two to three. February -- well,</p> <p>4 let's see. January, in that range, three months, three</p> <p>5 to four months.</p> <p>6 Q. So maybe December 2014, January 20 --</p> <p>7 A. No, December '15 into January '16, yes.</p> <p>8 Q. So December '15 into January 16, I'd like to</p> <p>9 focus on that time frame.</p> <p>10 A. Okay.</p> <p>11 Q. In that time frame and in preparing your</p> <p>12 report for this case, did you review any patient</p> <p>13 brochures?</p> <p>14 A. No.</p> <p>15 Q. In that time frame and in the preparation of</p> <p>16 your report for this case, did you review any IFUs for</p> <p>17 any of the TVT products?</p> <p>18 A. No.</p> <p>19 Q. In that time frame in the preparation of your</p> <p>20 report, did you review any specific scientific articles?</p> <p>21 MR. DIPOLA: Object to form; vague.</p> <p>22 A. Yes.</p> <p>23 Q. How would I discern which ones you reviewed?</p> <p>24 Would those be the ones listed in the body of your</p>



<p style="text-align: right;">Page 82</p> <p>1 report?</p> <p>2 A. Some. I looked at the Cochrane review</p> <p>3 articles in there. Those were probably the majority of</p> <p>4 what I looked at.</p> <p>5 Q. When you say you looked at the Cochrane</p> <p>6 review, you cite in your report to the Ogah study from</p> <p>7 2011, correct?</p> <p>8 A. Correct.</p> <p>9 Q. Is there a reason you didn't choose to cite to</p> <p>10 the Ford-Cochrane review from 2015?</p> <p>11 A. No.</p> <p>12 Q. Did you understand that that existed?</p> <p>13 A. Yes.</p> <p>14 Q. Have you reviewed the Nambiar-Cochrane review</p> <p>15 on single-incision slings from 2014?</p> <p>16 MR. DIPAOLA: Object to form.</p> <p>17 A. No.</p> <p>18 Q. Would it be fair to say that the bulk of your</p> <p>19 expert report focuses on the TVT Retropubic device?</p> <p>20 MR. DIPAOLA: Object to form.</p> <p>21 A. No.</p> <p>22 Q. Would you be surprised that the word</p> <p>23 "obturator" only shows up twice in your report?</p> <p>24 MR. DIPAOLA: Object.</p>	<p style="text-align: right;">Page 84</p> <p>1 Q. It gets loud at my house on Christmas.</p> <p>2 Do you believe there are differences between</p> <p>3 the mesh used in the TVT slings and the mesh that's used</p> <p>4 in the AMS slings?</p> <p>5 A. Yes.</p> <p>6 Q. What do you believe those differences to be?</p> <p>7 A. The laser cut of the slings with Ethicon</p> <p>8 versus the AMS products.</p> <p>9 Q. The AMS products are mechanically cut?</p> <p>10 A. I think so, yes.</p> <p>11 Q. Do you find there is a difference in the</p> <p>12 characteristics between a laser cut mesh and a</p> <p>13 mechanically cut mesh?</p> <p>14 A. Visibly, yes. Clinically, no.</p> <p>15 Q. Is it a decision-making point for you ever</p> <p>16 when you're deciding to use a particular device whether</p> <p>17 it's laser cut or mechanically cut?</p> <p>18 A. No.</p> <p>19 Q. Do you believe that in your hands a laser cut</p> <p>20 mesh is a little stiffer than a mechanically cut mesh?</p> <p>21 MR. DIPAOLA: Object to form.</p> <p>22 A. No.</p> <p>23 Q. Have you ever seen documents that demonstrate</p> <p>24 the different characteristics of mechanically cut mesh</p>
<p style="text-align: right;">Page 83</p> <p>1 A. No.</p> <p>2 Q. Do you think that your report is focused on</p> <p>3 the TVT Obturator?</p> <p>4 MR. DIPAOLA: Object; asked and answered.</p> <p>5 A. I think it's focused on synthetic slings used</p> <p>6 for stress incontinence.</p> <p>7 Q. Do you believe it's focused on</p> <p>8 Ethicon-manufactured synthetic slings for stress urinary</p> <p>9 incontinence?</p> <p>10 A. Yes.</p> <p>11 Q. When you're making a decision between using an</p> <p>12 Ethicon mesh or an AMS mesh, what drives your decision?</p> <p>13 MR. DIPAOLA: Object to form.</p> <p>14 A. You're talking about slings?</p> <p>15 Q. I'm talking about slings. Thank you.</p> <p>16 A. Okay. Experience, data.</p> <p>17 Q. What do you find to be the differences --</p> <p>18 MR. DIPAOLA: Were you done with your answer?</p> <p>19 Were you done?</p> <p>20 THE WITNESS: Yeah.</p> <p>21 Q. And if I interrupt, please interrupt back.</p> <p>22 A. I will, I will.</p> <p>23 Q. It's the Italian in me.</p> <p>24 A. I understand.</p>	<p style="text-align: right;">Page 85</p> <p>1 and laser cut mesh?</p> <p>2 A. No.</p> <p>3 Q. Have you ever seen Ethicon's internal bench</p> <p>4 testing showing the difference in elasticity between</p> <p>5 laser cut and mechanically cut mesh?</p> <p>6 MR. DIPAOLA: Object to form; asked and</p> <p>7 answered.</p> <p>8 A. No.</p> <p>9 Q. When you use a TVT Obturator product -- do you</p> <p>10 still use TVT Obturators today?</p> <p>11 A. Yes.</p> <p>12 Q. When you use a TVT Obturator product, do you</p> <p>13 specifically request the laser cut version of the TVT-O?</p> <p>14 A. No.</p> <p>15 Q. Do you request a mechanically cut version?</p> <p>16 A. No.</p> <p>17 Q. Do you know which it is that you receive when</p> <p>18 you get a TVT Obturator?</p> <p>19 A. With the Monarc, I do. With the TVT Abbrevio,</p> <p>20 I do.</p> <p>21 Q. What about with --</p> <p>22 A. And with TVT Exact, I do.</p> <p>23 Q. What about with the TVT Obturator?</p> <p>24 A. We don't use the TVT Obturator anymore.</p>

<p style="text-align: right;">Page 86</p> <p>1 Q. Okay. I'm sorry. When was the last time you 2 used a TVT Obturator?</p> <p>3 A. Probably four or five years ago. When Abbrevio 4 came out, I guess, whenever that came out.</p> <p>5 Q. So when Abbrevio came out in 2009 or '10, that 6 was the last time you used a TVT Obturator?</p> <p>7 A. Correct.</p> <p>8 Q. The full-length --</p> <p>9 A. The full-length inside-out Ethicon product.</p> <p>10 Q. Is the same true for TVT Retropubic and the 11 Exact, that is, that once the Exact came out, you 12 stopped use the retropubic device?</p> <p>13 A. Yes.</p> <p>14 Q. Why did you stop use the TVT Obturator when 15 the Abbrevio came out?</p> <p>16 MR. DIPOLA: Object to form.</p> <p>17 A. The Abbrevio data showed the same effect, and 18 our data with our patients showed the same effect, or my 19 data, and it was in our opinion, or my opinion, less 20 groin pain. So with the same effect, less pain, we 21 started using the Abbrevio.</p> <p>22 Q. Did you ever implant a TVT Obturator 23 full-length sling after you started to use the Abbrevio?</p> <p>24 A. Actually, I have not.</p>	<p style="text-align: right;">Page 88</p> <p>1 five minutes for me. Thank you.</p> <p>2 MR. ZONIES: I need to take another break. 3 (Short recess taken.)</p> <p>4 BY MR. ZONIES:</p> <p>5 Q. Doctor, before the break, we were discussing 6 your use of various obturator slings. Do you recall 7 that?</p> <p>8 A. Yes.</p> <p>9 Q. So I want to be sure that I understand your 10 current practice. If a patient presents to you and you 11 believe it's best that they get an obturator sling 12 implanted, it sounds to me like you choose either the 13 TVT Abbrevio or the Monarc; is that correct?</p> <p>14 A. That's correct.</p> <p>15 Q. And the Monarc is the full-length sling that's 16 made by AMS, correct?</p> <p>17 A. Correct.</p> <p>18 Q. You do not use the TVT Obturator device in 19 your practice, correct?</p> <p>20 A. Now.</p> <p>21 Q. Now.</p> <p>22 A. Yeah, correct.</p> <p>23 Q. And you haven't used that since TVT Abbrevio 24 came onto the market, correct?</p>
<p style="text-align: right;">Page 87</p> <p>1 Q. Can you think of any particular reason why a 2 patient, a particular patient, would call for a TVT 3 Obturator full-length sling instead of an Abbrevio?</p> <p>4 A. Yes.</p> <p>5 Q. What is that situation?</p> <p>6 A. Somebody who has lower leak point pressures, 7 or somebody who has more hypermobility than you would 8 like with an Abbrevio.</p> <p>9 Q. What is the difference between the Abbrevio and 10 the TVT Obturator that you think makes one better than 11 the other in those situations?</p> <p>12 MR. DIPOLA: Object to form.</p> <p>13 A. The Abbrevio is the pain, I think. There's 14 less pain in the groin.</p> <p>15 Q. But you also said that there might be a reason 16 to use an obturator.</p> <p>17 A. A long -- yes.</p> <p>18 Q. If --</p> <p>19 A. I guess -- let me clarify it. I still use 20 long obturators; but in that situation, I use a Monarc 21 outside-in AMS product. So I'm still using the long 22 one. I'm not just using Abbrevio as a TOT. Does that 23 make sense?</p> <p>24 Q. It does. That actually clarifies the last</p>	<p style="text-align: right;">Page 89</p> <p>1 A. Correct.</p> <p>2 Q. One of the reasons that you chose to switch 3 over to the TVT Abbrevio is your belief that it had 4 similar outcomes as the TVT Obturator, full length, from 5 Ethicon but exhibited less groin and thigh pain, 6 correct?</p> <p>7 A. Correct.</p> <p>8 Q. So, for you, that is the chosen TVT device, 9 Ethicon device, to use in the obturator approach, 10 correct?</p> <p>11 MR. DIPOLA: Object to form.</p> <p>12 A. To a certain extent. When Abbrevio came out, I 13 thought, and I was under the impression, that they 14 weren't going to market the TVT-O anymore. And, in 15 fact, I just found out last week from some doctors in 16 Dayton that they still do. But at our hospital, we 17 didn't stock it. Once Abbrevio came out, they stopped 18 stocking TVT-O, and I just assumed that TVT-O was off 19 the market, but apparently it isn't. So now if we can 20 get it, I will get it, and I will probably start using 21 it again.</p> <p>22 Q. In your current practice, when you want to use 23 a full-length sling, you choose the AMS product, 24 correct?</p>

<p style="text-align: right;">Page 90</p> <p>1 A. Because that's the only one we have.</p> <p>2 Q. The only full-length obturator sling that you</p> <p>3 have available?</p> <p>4 A. At our hospital, yes.</p> <p>5 Q. If you do decide to get the TVT Obturator into</p> <p>6 your hospital and you can manage to do so, will you</p> <p>7 specifically request the laser cut version of the TVT</p> <p>8 Obturator?</p> <p>9 MR. DIPAOLA: Object to form.</p> <p>10 A. Yes.</p> <p>11 Q. What is it that you like about the laser cut</p> <p>12 of the mesh as compared to the mechanically cut mesh?</p> <p>13 A. Visibly it looks cleaner when you're putting</p> <p>14 it in the space. It is, in my opinion, easier to</p> <p>15 tension because of the way the edges are cut versus a</p> <p>16 mechanical cut. Those are probably the two biggest</p> <p>17 reasons.</p> <p>18 Q. When you were using mechanically cut TVT</p> <p>19 devices, you noticed that the edges were sometimes</p> <p>20 frayed, for example?</p> <p>21 MR. DIPAOLA: Object to form.</p> <p>22 A. I wouldn't say frayed. They looked different</p> <p>23 than a laser cut.</p> <p>24 Q. They were -- I've heard it described sometimes</p>	<p style="text-align: right;">Page 92</p> <p>1 TVT Retropubic; is that correct?</p> <p>2 A. No.</p> <p>3 MR. DIPAOLA: Object to form.</p> <p>4 A. No, TVT Exact is not a shorter sling.</p> <p>5 Q. When you started to use the TVT Exact, you</p> <p>6 stopped using the TVT Retropubic; is that correct?</p> <p>7 A. The original TVT Retropubic, it was just the</p> <p>8 introduction device is different, and the introducer is</p> <p>9 different.</p> <p>10 Q. I apologize.</p> <p>11 A. Okay.</p> <p>12 Q. I'm mixing up my Abbrevos and all --</p> <p>13 A. That's okay.</p> <p>14 Q. When you started to use the TVT Exact, did you</p> <p>15 completely stop using the TVT Retropubic, the original?</p> <p>16 A. Yes.</p> <p>17 Q. And assuming the TVT Retropubic original is</p> <p>18 still available on the market, is it something that you</p> <p>19 would choose to use today, or is it not available in</p> <p>20 your --</p> <p>21 A. It is still available --</p> <p>22 MR. DIPAOLA: Object to form.</p> <p>23 A. -- but I don't choose to use it anymore.</p> <p>24 Q. What was the primary driver for you to stop</p>
<p style="text-align: right;">Page 91</p> <p>1 as sharper. Is that fair?</p> <p>2 MR. DIPAOLA: Object to form.</p> <p>3 A. I wouldn't say sharper. I would just say it</p> <p>4 looks physically different.</p> <p>5 Q. Did you ever experience particle loss, blue</p> <p>6 pieces of polypropylene in the packaging or in the body</p> <p>7 as you were implanting a device?</p> <p>8 A. I never experienced that.</p> <p>9 Q. You didn't see a difference between the</p> <p>10 mechanically cut mesh and the particle loss as compared</p> <p>11 to the laser cut mesh?</p> <p>12 MR. DIPAOLA: Object to form.</p> <p>13 A. No.</p> <p>14 Q. You've never seen any internal Ethicon</p> <p>15 documents discussing those differences between the laser</p> <p>16 cut mesh and the mechanically cut mesh, correct?</p> <p>17 MR. DIPAOLA: Asked and answered.</p> <p>18 A. I have not.</p> <p>19 Q. With regard to the TVT Retropubic device, I</p> <p>20 believe you testified that you used the TVT Retropubic</p> <p>21 device until the TVT Exact came to market, correct?</p> <p>22 A. Correct.</p> <p>23 Q. Then when the TVT Exact came to market, which</p> <p>24 is a shorter sling, you stopped using the full-length</p>	<p style="text-align: right;">Page 93</p> <p>1 using the TVT Retropubic?</p> <p>2 A. The original TVT?</p> <p>3 MR. DIPAOLA: Object to form.</p> <p>4 A. Because TVT Exact is a TVT Retropubic.</p> <p>5 Q. We call them TVT-R and TVT-E.</p> <p>6 A. Okay. All right.</p> <p>7 Q. So I'll ask it cleaner.</p> <p>8 A. Okay. Go ahead.</p> <p>9 Q. What was the primary driver for you to stop</p> <p>10 using the original TVT Retropubic and move to the TVT</p> <p>11 Exact device?</p> <p>12 A. The tactile sensation with the new device was</p> <p>13 much better. We also have a fellowship program where</p> <p>14 we're teaching fellows and residents how to do these</p> <p>15 types of procedures. And from a teaching standpoint, it</p> <p>16 was a much easier procedure to teach because of the</p> <p>17 tactile sensation that you feel as you're going behind</p> <p>18 the retropubic bone. And in my experience, I saw less</p> <p>19 bladder injuries at the time of insertion, but that's</p> <p>20 just my experience, especially teaching residents and</p> <p>21 fellows. So those were the reasons why we went through</p> <p>22 the transition to TVT-E.</p> <p>23 Q. So it sounds like the primary drivers for</p> <p>24 switching to the TVT-E were the ease of use during the</p>

<p style="text-align: right;">Page 94</p> <p>1 operative procedure and the fewer complications; in</p> <p>2 particular, bladder perforations, correct?</p> <p>3 A. Correct.</p> <p>4 Q. And the TVT Retropubic, the original one, is</p> <p>5 still available for you to use; however, you haven't</p> <p>6 used it since the introduction of the TVT Exact?</p> <p>7 A. That's correct.</p> <p>8 Q. In your expert report, there's a section</p> <p>9 shortly after that starts with "Results and References."</p> <p>10 Do you see that?</p> <p>11 A. I do.</p> <p>12 Q. This goes on for five and a half, six pages,</p> <p>13 correct?</p> <p>14 A. Correct.</p> <p>15 Q. When you wrote this section of your report</p> <p>16 entitled "Results and References," were these -- as we</p> <p>17 discussed earlier, were these the main reference</p> <p>18 materials that you rely upon in offering your opinions</p> <p>19 in this case?</p> <p>20 MR. DIPOLA: Object to form.</p> <p>21 A. They're the ones that I listed, but I rely on</p> <p>22 all my background teachings and what I've learned in my</p> <p>23 experience throughout my career, and a lot of these are</p> <p>24 similar studies that regurgitate the same thing that we</p>	<p style="text-align: right;">Page 96</p> <p>1 and I thought that the information there was very</p> <p>2 relevant and prevalent.</p> <p>3 Q. I've got the study. Let me go ahead and pull</p> <p>4 it out.</p> <p>5 - - -</p> <p>6 ARTICLE ENTITLED, "RETROPUBIC</p> <p>7 VERSUS TRANSOBTURATOR MIDURETHRAL</p> <p>8 SLINGS FOR STRESS INCONTINENCE" WAS</p> <p>9 MARKED AS EXHIBIT NO. 8.</p> <p>10 - - -</p> <p>11 Q. Doctor, I'm marking Exhibit 8, which is the</p> <p>12 study in the New England Journal of Medicine entitled</p> <p>13 "Retropubic Versus Transobturator Midurethral Slings for</p> <p>14 Stress Incontinence" with the lead author being Richter,</p> <p>15 R-i-c-h-t-e-r, and it is commonly known as the TOMUS</p> <p>16 study, T-O-M-U-S; is that right?</p> <p>17 A. That's correct.</p> <p>18 Q. You felt this paper was reflective of your</p> <p>19 opinions in this case, and you relied upon it, correct?</p> <p>20 A. Yes.</p> <p>21 Q. The paper has a finding in the conclusions</p> <p>22 that "The rates of subjectively assessed success were</p> <p>23 similar between groups but did not meet the criteria for</p> <p>24 equivalence." Is that correct?</p>
<p style="text-align: right;">Page 95</p> <p>1 found in previous studies.</p> <p>2 So I can say these are probably the ones that</p> <p>3 I utilized the most, but I also, you know, rely on my</p> <p>4 textbooks, my past experience, all the journal articles</p> <p>5 that I've read, and I get about six journals in this</p> <p>6 field, and so you're always reading abstracts and</p> <p>7 reading things that catch your eye, yes.</p> <p>8 Q. But when writing your report, these were the</p> <p>9 ones that you felt comfortable as capturing your</p> <p>10 opinions essentially?</p> <p>11 MR. DIPOLA: Object to form.</p> <p>12 A. These were the majority of them, yes.</p> <p>13 Q. One of the first studies you talk about is the</p> <p>14 Cochrane study that we discussed, the Ogah study,</p> <p>15 correct?</p> <p>16 A. Correct.</p> <p>17 Q. And you go on to discuss the TOMUS, T-O-M-U-S,</p> <p>18 study. Richter, R-i-c-h-t-e-r, is the lead author on</p> <p>19 that study, correct?</p> <p>20 A. Right.</p> <p>21 Q. Why did you choose to discuss the TOMUS study?</p> <p>22 A. That was a study that was supported by the</p> <p>23 AUGS federation and their group, and it was a very</p> <p>24 well-designed study that looked at midurethral slings,</p>	<p style="text-align: right;">Page 97</p> <p>1 A. That's what it says, yes.</p> <p>2 Q. So in this paper, if you look in the "Results"</p> <p>3 section, it states that -- in the "Abstract." Sorry.</p> <p>4 It states that "The rates of subjectively assessed</p> <p>5 success were 62.2 percent and 55.8 percent,</p> <p>6 respectively," the first being retropubic and the second</p> <p>7 being transobturator, correct?</p> <p>8 A. Correct.</p> <p>9 Q. So the failure rate for the transobturators in</p> <p>10 this study was roughly 44 percent, correct?</p> <p>11 MR. DIPOLA: Object to form.</p> <p>12 A. Yes.</p> <p>13 Q. Do you believe that correctly reflects the</p> <p>14 failure rates for TVT Obturators?</p> <p>15 MR. DIPOLA: Object to form.</p> <p>16 A. Not in my hands, no.</p> <p>17 Q. But you chose to cite to this study, correct?</p> <p>18 A. I did cite this study, correct.</p> <p>19 Q. And this study also stands for the proposition</p> <p>20 that TVT Retropubic has a higher success rate than does</p> <p>21 TVT Obturator, correct?</p> <p>22 MR. DIPOLA: Object to form.</p> <p>23 A. I don't -- did they -- I don't think that was</p> <p>24 clinically significant.</p>

<p style="text-align: right;">Page 98</p> <p>1 Q. It failed to show equivalency, correct?</p> <p>2 A. Yeah, but that doesn't necessarily mean that</p> <p>3 it's clinically significant.</p> <p>4 Q. What do you mean by that?</p> <p>5 A. Well, what were their confidence intervals and</p> <p>6 did their confidence intervals show a P value for a</p> <p>7 result that was clinically significant?</p> <p>8 Q. Do you see in the "Methods" section, the last</p> <p>9 sentence, "The predetermined equivalence margin was plus</p> <p>10 or minus 12 percentage points"?</p> <p>11 A. Okay.</p> <p>12 Q. Do you see that?</p> <p>13 A. Yes, I do.</p> <p>14 Q. So do you know what an equivalency study is?</p> <p>15 A. I don't know what this exactly means, that</p> <p>16 they were a predetermined equivalence margin. It's a</p> <p>17 statistical term that I'm not familiar with.</p> <p>18 Q. Okay. Do you know what a non-inferiority</p> <p>19 study is?</p> <p>20 A. Yes.</p> <p>21 Q. If you turn to page 8 of the study, it has an</p> <p>22 adverse events chart.</p> <p>23 A. Yes.</p> <p>24 Q. If you look at the adverse event chart for the</p>	<p style="text-align: right;">Page 100</p> <p>1 Q. And you talked about one other one. Did you</p> <p>2 say extrusion?</p> <p>3 A. Extrusion and exposure, I think, are used</p> <p>4 simultaneously. Erosion, I think most people would say</p> <p>5 is into a viscus.</p> <p>6 Q. And what about a perforation?</p> <p>7 A. That's different.</p> <p>8 Q. How is a perforation different?</p> <p>9 A. You don't perforate with a mesh. You</p> <p>10 perforate with an introducer.</p> <p>11 Q. So further down in this chart they talk about</p> <p>12 perforations. Those would be from the trocars?</p> <p>13 A. Correct, the introducers.</p> <p>14 Q. On the next page of your expert report is the</p> <p>15 first, I think, in a series of photographs of a computer</p> <p>16 screen, correct?</p> <p>17 A. Correct.</p> <p>18 Q. How was that photograph generated?</p> <p>19 A. My phone.</p> <p>20 Q. You took a picture of your computer screen</p> <p>21 with your phone?</p> <p>22 A. Yes.</p> <p>23 Q. That is old school.</p> <p>24 The study that you present here is only TVT</p>
<p style="text-align: right;">Page 99</p> <p>1 retropubic sling, it has nine events of a mesh exposure</p> <p>2 in eight patients. Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. For 2.7 percent of the patients having an</p> <p>5 exposure. Is that consistent with your practice?</p> <p>6 MR. DIPOLA: Object to form.</p> <p>7 A. Okay. So let me see. No. I have a lower</p> <p>8 rate of mesh exposure in my practice.</p> <p>9 Q. And then it also has mesh erosion underneath</p> <p>10 that?</p> <p>11 A. Um-hmm.</p> <p>12 Q. Yes?</p> <p>13 A. Yes. Sorry.</p> <p>14 Q. What's the difference between exposure and</p> <p>15 erosion?</p> <p>16 A. I think it depends on what surgeon you're</p> <p>17 talking to or what group you're talking to. In my</p> <p>18 opinion, an erosion is an erosion into a viscus, which</p> <p>19 would be the bladder or the bowel. An extrusion would</p> <p>20 be into the vagina. That's how I describe the two.</p> <p>21 So I'm not real sure what they were referring</p> <p>22 to as an erosion. Most likely, I would think they were</p> <p>23 referring to the same thing since they have both erosion</p> <p>24 and exposure.</p>	<p style="text-align: right;">Page 101</p> <p>1 Retropubic, correct?</p> <p>2 A. That is correct.</p> <p>3 Q. On the next page, you have rates of surgical</p> <p>4 cure. Can you describe for me what that slide shows?</p> <p>5 A. Yes. This is a slide that was used in, again,</p> <p>6 a teaching program showing the different historical</p> <p>7 rates, average rates, of what we would consider cured or</p> <p>8 subjective cure for the different procedures that have</p> <p>9 been used historically. Anterior colporrhaphy, average</p> <p>10 was 60 percent. Retropubic colposuspension would either</p> <p>11 be a Burch or an MMK. That was 84 percent. And needle</p> <p>12 urethropexy would be like a Stamey or a Pereyra,</p> <p>13 88 percent. And then you have the synthetic slings,</p> <p>14 which would be TVT and TVT-O or TOT Obturator, which</p> <p>15 would be 88 percent. And then the last one would be a</p> <p>16 pubovaginal fascial sling, which would be 81 percent.</p> <p>17 Q. Have you performed all of these at one time in</p> <p>18 your career?</p> <p>19 A. Yes. Well, actually, no. I've performed</p> <p>20 anterior colporrhaphy, but I did not perform it for the</p> <p>21 treatment of stress incontinence.</p> <p>22 Q. What did you perform that for?</p> <p>23 A. For an anterior cystocele.</p> <p>24 Q. You've said that you've done 2,000 slings or</p>



<p style="text-align: right;">Page 102</p> <p>1 so.</p> <p>2 A. Approximately, yes.</p> <p>3 Q. Do you also do prolapse repairs?</p> <p>4 A. Yes.</p> <p>5 MR. DIPAOLA: Object to form.</p> <p>6 Q. Do you use synthetic meshes in your prolapse</p> <p>7 repairs?</p> <p>8 MR. DIPAOLA: Object to form; beyond the</p> <p>9 scope.</p> <p>10 A. I have, yes.</p> <p>11 Q. How many POP procedures with a synthetic mesh</p> <p>12 do you think you've done over your career?</p> <p>13 MR. DIPAOLA: Same objection.</p> <p>14 A. 300, 350.</p> <p>15 Q. Not nearly as many as slings?</p> <p>16 A. No.</p> <p>17 MR. DIPAOLA: Object.</p> <p>18 A. No.</p> <p>19 Q. The presentation that we're looking at that is</p> <p>20 a photograph using your phone of your computer screen,</p> <p>21 that presentation, I presume, resides on your computer,</p> <p>22 correct?</p> <p>23 A. Parts of it, yes.</p> <p>24 Q. So that's something that, if I requested it,</p>	<p style="text-align: right;">Page 104</p> <p>1 A. Yes.</p> <p>2 Q. This is the 2002 Hilton. Were there later</p> <p>3 Ward and Hilton studies of this same population?</p> <p>4 A. I'm not aware of them.</p> <p>5 Q. And this is, because it's 2002, limited to the</p> <p>6 TVT Retropubic, correct?</p> <p>7 A. Correct.</p> <p>8 Q. There's nothing in this study nor in the Kuuva</p> <p>9 and Nilsson study we were looking at about the TVT</p> <p>10 Obturator?</p> <p>11 A. That's correct.</p> <p>12 Q. And you would agree with your own slide that</p> <p>13 you're presenting here that bladder injury is more</p> <p>14 common with the TVT than with the Burch, correct?</p> <p>15 MR. DIPAOLA: Object to form.</p> <p>16 A. Repeat that question.</p> <p>17 Q. Sure. The slide we were just looking at from</p> <p>18 Ward and Hilton says -- the quote you're putting in this</p> <p>19 slide is "Bladder injury is more common with TVT than</p> <p>20 Burch," correct?</p> <p>21 A. That's an interesting question. I guess the</p> <p>22 question is, with a TVT, you get the bladder injury from</p> <p>23 the introducer. During a Burch procedure, we always</p> <p>24 injure the bladder. So I'm having a hard time</p>
<p style="text-align: right;">Page 103</p> <p>1 we could get a drive with your presentation on it?</p> <p>2 MR. DIPAOLA: Object to form. We'll take it</p> <p>3 under advisement should the request come.</p> <p>4 A. It wasn't my presentation, but it is a</p> <p>5 presentation on my computer, yes.</p> <p>6 Q. You told me whose presentation this was.</p> <p>7 A. Mark Walters.</p> <p>8 Q. Okay. Is this a presentation he typically</p> <p>9 gives with your brother?</p> <p>10 A. Not necessarily.</p> <p>11 Q. In addition to this presentation, do you have</p> <p>12 other presentations that you've created and presented on</p> <p>13 your computer as well?</p> <p>14 MR. DIPAOLA: Object to form.</p> <p>15 A. Or other presentations that other doctors have</p> <p>16 presented, yes.</p> <p>17 Q. And those are available on your computer, or</p> <p>18 you could pull those up and shoot a photo with your</p> <p>19 phone as well?</p> <p>20 MR. DIPAOLA: Object to form.</p> <p>21 A. Probably.</p> <p>22 Q. On the next page, you have a screenshot of the</p> <p>23 Ward and Hilton study, 2002, comparing Burch to TVT,</p> <p>24 correct?</p>	<p style="text-align: right;">Page 105</p> <p>1 distinguishing the two. And the reason we do that is</p> <p>2 because when we do Burch, we use a permanent suture, and</p> <p>3 so before we close the abdomen, we have to open up the</p> <p>4 bladder so that we can see if the sutures are in the</p> <p>5 bladder or not.</p> <p>6 So at that point, we open up the bladder, so</p> <p>7 that would theoretically be a bladder injury. Check to</p> <p>8 make sure the sutures are not in the bladder, put the</p> <p>9 suprapubic catheter in, close the bladder, and that</p> <p>10 would be the Burch.</p> <p>11 So theoretically if you say that's a bladder</p> <p>12 injury, then we injure the bladder every time we do a</p> <p>13 Burch. But I think they are referring to the actual</p> <p>14 technique of the TVT versus the technique of the Burch.</p> <p>15 Q. So if you wanted to make this more clear in</p> <p>16 your report, would it be fair to say -- add the phrase</p> <p>17 "inadvertent bladder injury"?</p> <p>18 A. Correct.</p> <p>19 Q. Gotcha. So just to be sure I've got it then,</p> <p>20 you would take the last bullet point and say inadvertent</p> <p>21 bladder injury is more common with TVT than with Burch?</p> <p>22 A. That's correct.</p> <p>23 Q. On the next page, you have a slide that's</p> <p>24 entitled "TVT Long-Term Follow-up Data." Do you see</p>

<p style="text-align: right;">Page 106</p> <p>1 that?</p> <p>2 A. Yes.</p> <p>3 Q. And, again, this is citing five studies.</p> <p>4 Those are all only about the TVT Retropubic, not the TVT</p> <p>5 Obturator, correct?</p> <p>6 A. That's correct.</p> <p>7 Q. In the Olson study, the last Olson, with one</p> <p>8 S, do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. The last one on the slide --</p> <p>11 A. Yes.</p> <p>12 Q. -- has various percentages; dry, 77 percent,</p> <p>13 improved, 18 percent; failed, 15 percent. That adds up</p> <p>14 to 110 percent. Do you have a sense of where the</p> <p>15 mistake is there?</p> <p>16 A. No, I don't.</p> <p>17 Q. You would agree that that appears to be an</p> <p>18 error?</p> <p>19 A. Unless -- it depends on how they defined dry,</p> <p>20 improved and failed.</p> <p>21 Q. Whether or not they overlapped?</p> <p>22 A. Correct.</p> <p>23 Q. Then for the Rezapour study -- let me ask</p> <p>24 this. This is a presentation that you've given to other</p>	<p style="text-align: right;">Page 108</p> <p>1 their legal department.</p> <p>2 Q. And if we turn back to your report, Doctor,</p> <p>3 the chart we were just looking at, if you look just</p> <p>4 above Olson, there's Rezapour, R-e-z-a-p-o-u-r. Do you</p> <p>5 see that?</p> <p>6 A. Yes.</p> <p>7 Q. If you add those percentages up, it adds up to</p> <p>8 94 percent. Do you know why that is?</p> <p>9 A. Again, I would have to look at how they</p> <p>10 distinguished, and maybe there were some overlaps.</p> <p>11 ---</p> <p>12 ARTICLE ENTITLED, "TENSION-FREE</p> <p>13 VAGINAL TAPE (TVT) IN WOMEN WITH</p> <p>14 RECURRENT STRESS URINARY</p> <p>15 INCONTINENCE - A LONG-TERM FOLLOW</p> <p>16 UP" WAS MARKED AS EXHIBIT NO. 9.</p> <p>17 ---</p> <p>18 Q. I'm going to hand you Exhibit 9, which is the</p> <p>19 Rezapour study.</p> <p>20 A. Okay.</p> <p>21 Q. And if you look just in the "Abstract"</p> <p>22 section, the last sentence of the first paragraph</p> <p>23 starting with the word "According," are you with me?</p> <p>24 A. The last --</p>
<p style="text-align: right;">Page 107</p> <p>1 physicians, correct?</p> <p>2 A. I've used this slide, yes.</p> <p>3 Q. Have you used this slide in professional</p> <p>4 education?</p> <p>5 A. I don't think I have, because all the</p> <p>6 professional education slides were given to us by the</p> <p>7 company, and we had to use their slide decks, and I'm</p> <p>8 not real sure if this was in their slide deck.</p> <p>9 Q. That's a good point, Doctor. So when you were</p> <p>10 acting as a consultant for Ethicon and speaking on</p> <p>11 Ethicon's behalf, the materials that you presented were</p> <p>12 created and provided to you by Ethicon, correct?</p> <p>13 A. That's correct.</p> <p>14 Q. Were you permitted to make changes to those</p> <p>15 materials?</p> <p>16 MR. DIPOLA: Object to form.</p> <p>17 A. If we did, it had to go through their legal</p> <p>18 department, and they had to approve it before, and I'm</p> <p>19 not aware of ever making any changes.</p> <p>20 Q. So you weren't permitted to make any changes</p> <p>21 to the materials provided to you by Ethicon --</p> <p>22 MR. DIPOLA: Object to form; misstates.</p> <p>23 Q. -- is that correct?</p> <p>24 A. We couldn't change it unless we went through</p>	<p style="text-align: right;">Page 109</p> <p>1 Q. "Abstract."</p> <p>2 A. The last sentence in the paragraph?</p> <p>3 Q. In the first paragraph, yeah.</p> <p>4 A. Oh, okay. Yes, yes.</p> <p>5 Q. If you look at the Rezapour study, Exhibit 9,</p> <p>6 Doctor, it says, "According to the protocol, 28 patients</p> <p>7 (82%) were cured, 3 (9%) were significantly improved,</p> <p>8 and the operation failed in 3 cases (9%)." So your</p> <p>9 slide that you put in your expert report undervalues or</p> <p>10 understates the failure rate by -- it should be</p> <p>11 9 percent, not 3 percent, correct?</p> <p>12 A. Correct.</p> <p>13 Q. So that slide has, it appears, two errors in</p> <p>14 it, correct?</p> <p>15 A. Yes, depending on the definition, and it</p> <p>16 should also be that this study was a study on TVT on</p> <p>17 women with recurrent stress incontinence, not the</p> <p>18 primary procedure; whereas, the other studies were</p> <p>19 primary procedures. They weren't done on recurrent, to</p> <p>20 my knowledge. They were follow-ups on all the primary</p> <p>21 procedures.</p> <p>22 Q. So that's another change you'd want to make on</p> <p>23 that slide, is to make that notation?</p> <p>24 A. I would, yes.</p>



<p style="text-align: right;">Page 110</p> <p>1 Q. The next slide is Ulmsten's seminal study from  2 1999, correct?  3 A. Yes.  4 Q. Did you create this bar chart?  5 A. No.  6 Q. So this bar chart shows -- it appears to me  7 that this bar chart shows that there is an increase in  8 the number of women who were cured between 12 months and  9 24 to 36 months, correct?  10 A. That's correct.  11 ---  12 ARTICLE ENTITLED, "A THREE-YEAR  13 FOLLOW UP OF TENSION FREE VAGINAL  14 TAPE FOR SURGICAL TREATMENT OF  15 FEMALE STRESS URINARY INCONTINENCE"  16 WAS MARKED AS EXHIBIT NO. 10.  17 ---  18 Q. I'm going to hand you the Ulmsten study,  19 Exhibit 10. I'm handing that to you now, Doctor.  20 You'll see Exhibit 10, Doctor, is Ulmsten's 1999 study  21 entitled, "A three-year follow up of tension-free  22 vaginal tape for surgical treatment of female stress  23 urinary incontinence," correct?  24 A. Correct.</p>	<p style="text-align: right;">Page 112</p> <p>1 A. It was probably in a different presentation  2 but within the same format of teaching.  3 Q. That was my next question. Do you know if  4 this slide was used during a professional education?  5 A. No.  6 Q. No, you don't know, or no --  7 A. No, I don't know.  8 Q. Okay. And this slide, it appears, would also  9 be available on your computer; is that fair?  10 A. Yes.  11 Q. And if I needed to get a hold of it, I can ask  12 your counsel and they can provide that to me, correct?  13 A. Correct.  14 Q. So you would agree --  15 A. Actually, I think you can get it anywhere. It  16 was used in an AUGS teaching, and they put out a whole  17 teaching manual of every lecture that was given. So all  18 the lectures are in it.  19 Q. Did you create this slide?  20 A. No.  21 Q. But you think it was a slide that was  22 presented at AUGS by someone?  23 A. At one of the AUGS teaching programs, yes.  24 Q. And if that slide, indeed, reflects what it</p>
<p style="text-align: right;">Page 111</p> <p>1 Q. If you take a minute and turn to the fifth  2 page, it's page 349 of the study. Are you with me?  3 A. I'm getting there. Yes.  4 Q. If you look at Figure 4 on page 349, it  5 appears to me to be the same data and the same layout as  6 in your expert report, correct?  7 A. Yes.  8 Q. And you'd agree with me that at 12 months as  9 compared to the 24 to 36 months in the Ulmsten paper  10 itself, that it's actually the same number of women who  11 were cured, correct?  12 A. Correct.  13 Q. There's not an increase as is reflected in  14 your expert report, correct?  15 A. I'm not real sure that reflects that. I think  16 it's the -- I mean, it looks like that, but it might  17 just be the way that -- that was not intentional, I  18 guess I'm saying. My understanding is they were the  19 same between 12 and 24, just like it is here. So this  20 could be the way the slide was recreated. And I didn't  21 create this slide.  22 Q. Understood. Is this slide also part of the  23 same presentation that was reflected in the photographs  24 that you took of your computer?</p>	<p style="text-align: right;">Page 113</p> <p>1 looks like it reflects, which is an increase in cure  2 between months 12 and 24 to 36, it's incorrect?  3 MR. DIPOLA: Object to form.  4 A. If this slide was meant to be the slide in the  5 original paper, yes.  6 Q. Yes, it's incorrect?  7 A. Yes, it's incorrect.  8 Q. And you would want to correct that in your  9 report, correct?  10 MR. DIPOLA: Object to form; assumes facts  11 not in evidence.  12 A. Yes.  13 (Short recess taken.)  14 BY MR. ZONIES:  15 Q. Doctor, under the Ulmsten diagram, the next  16 section of your report is entitled "Company Training,"  17 correct?  18 A. Correct.  19 Q. In this section, you have a statement that  20 starts -- the last phrase on this page saying, "It is  21 well-known by all pelvic floor surgeons." Do you see  22 that?  23 A. Yes.  24 Q. You don't actually know that, right, that it's</p>

<p style="text-align: right;">Page 114</p> <p>1 well-known by all pelvic floor surgeons, correct?</p> <p>2 MR. DIPAOLA: Object to form.</p> <p>3 A. Well, I have never spoken personally with all</p> <p>4 pelvic surgeons, but I have worked with and trained a</p> <p>5 vast number of pelvic surgeons, and they are aware of</p> <p>6 certain things.</p> <p>7 Q. So would it be more accurate, for example, to</p> <p>8 say, "Of the pelvic surgeons I've worked with, it's my</p> <p>9 belief that ..." blank?</p> <p>10 A. No. I would say of all pelvic surgeons that</p> <p>11 are trained in pelvic surgery and have experience in</p> <p>12 pelvic surgery, it would be my belief that they would</p> <p>13 know whatever we're going to talk about.</p> <p>14 Q. But you don't have any personal knowledge?</p> <p>15 You haven't spoken to all pelvic surgeons, correct?</p> <p>16 MR. DIPAOLA: Object to form.</p> <p>17 A. No, I have not.</p> <p>18 Q. You go on to say that, "Any surgery for stress</p> <p>19 urinary incontinence or pelvic organ prolapse, with or</p> <p>20 without the use of mesh, can potentially cause</p> <p>21 complications that can be temporary or permanent,"</p> <p>22 correct?</p> <p>23 A. Correct.</p> <p>24 Q. And you then list certain complications,</p>	<p style="text-align: right;">Page 116</p> <p>1 MR. ZONIES: I'll move to strike that as</p> <p>2 nonresponsive.</p> <p>3 A. You are answering your question that I should</p> <p>4 have answered.</p> <p>5 Q. Right. So my question is, with what you have</p> <p>6 written --</p> <p>7 A. Correct.</p> <p>8 Q. -- is it true that surgery for stress urinary</p> <p>9 incontinence with the use of mesh can potentially cause</p> <p>10 permanent pelvic pain?</p> <p>11 MR. DIPAOLA: Object; mischaracterizes.</p> <p>12 A. No, that's not what I'm saying.</p> <p>13 Q. Is it true, Doctor, that what you're saying</p> <p>14 here is that surgery for stress urinary incontinence</p> <p>15 with or without mesh can cause permanent pelvic pain?</p> <p>16 A. Correct.</p> <p>17 Q. And, therefore, as a subset of that, isn't it</p> <p>18 also true that surgery for stress urinary incontinence</p> <p>19 with the use of mesh can cause permanent pelvic pain?</p> <p>20 MR. DIPAOLA: Same objection.</p> <p>21 A. Or without the use of mesh as well, as a</p> <p>22 subset, yes.</p> <p>23 Q. Both of those subsets are true, correct?</p> <p>24 A. Correct.</p>
<p style="text-align: right;">Page 115</p> <p>1 correct?</p> <p>2 A. Correct.</p> <p>3 Q. So if I'm reading my disjunctives correctly,</p> <p>4 if that's the right word, my "ors" correctly, that</p> <p>5 sentence could be read as "Any surgery for stress</p> <p>6 urinary incontinence or pelvic organ prolapse with the</p> <p>7 use of mesh can potentially cause complications that</p> <p>8 could be permanent," correct?</p> <p>9 MR. DIPAOLA: Object to form;</p> <p>10 mischaracterizes.</p> <p>11 A. Correct.</p> <p>12 Q. And included among those complications that</p> <p>13 with the use of mesh can be permanent, you list pelvic</p> <p>14 pain, correct?</p> <p>15 A. Correct.</p> <p>16 Q. So, in other words, a surgery for stress</p> <p>17 urinary incontinence with the use of mesh can cause</p> <p>18 permanent pelvic pain, correct?</p> <p>19 MR. DIPAOLA: Object to form.</p> <p>20 A. And surgery for stress urinary incontinence</p> <p>21 without mesh can cause pelvic pain permanent. That's</p> <p>22 what I'm saying, yes.</p> <p>23 Q. Right.</p> <p>24 A. Correct.</p>	<p style="text-align: right;">Page 117</p> <p>1 Q. So I'll ask it this way. Is it true, Doctor,</p> <p>2 that in your expert opinion, surgery for stress urinary</p> <p>3 incontinence without the use of mesh can potentially</p> <p>4 cause permanent pelvic pain?</p> <p>5 A. Yes.</p> <p>6 Q. Is it also true that surgery for stress</p> <p>7 urinary incontinence with the use of mesh can cause</p> <p>8 permanent pelvic pain?</p> <p>9 A. Yes.</p> <p>10 Q. Is it also true that surgery for stress</p> <p>11 urinary incontinence without the use of mesh, in your</p> <p>12 opinion, can cause permanent dyspareunia?</p> <p>13 A. Yes.</p> <p>14 Q. Is it your opinion, Doctor, to a reasonable</p> <p>15 degree of medical certainty that surgery for stress</p> <p>16 urinary incontinence with the use of mesh can cause</p> <p>17 permanent dyspareunia?</p> <p>18 MR. DIPAOLA: Object to form.</p> <p>19 A. Ask that question again.</p> <p>20 Q. Sure. Is it your opinion, Doctor, to a</p> <p>21 reasonable degree of medical certainty that surgery for</p> <p>22 stress urinary incontinence with the use of mesh or</p> <p>23 without can cause permanent dyspareunia?</p> <p>24 A. Yes.</p>

<p style="text-align: right;">Page 118</p> <p>1 Q. Is it also true for each of these outcomes 2 that you have here, that surgery for stress urinary 3 incontinence with the use of mesh can cause permanent 4 scarring, vaginal narrowing, leg/groin pain, urinary 5 retention and other voiding problems? 6 A. And without mesh, both of them, yes. 7 Q. So as a subset, is it your opinion that 8 surgery for stress urinary incontinence without the use 9 of mesh can cause permanent pelvic pain, dyspareunia, 10 scarring, vaginal narrowing, leg/groin pain, urinary 11 retention and other voiding problems? 12 A. Yes. 13 Q. Similarly, is it your opinion within a 14 reasonable degree of medical certainty that surgery for 15 stress urinary incontinence with the use of mesh can 16 cause permanent pelvic pain, dyspareunia, scarring, 17 vaginal narrowing, leg/groin pain, urinary retention and 18 other voiding problems? 19 MR. DIPAOLA: Object to form. 20 A. Yes. 21 Q. You go on to discuss in this section some of 22 the training that you've participated in, correct? 23 A. That's correct. 24 Q. You say, "The process would begin with</p>	<p style="text-align: right;">Page 120</p> <p>1 A. In my opinion, yes. 2 Q. And you also have the next sentence where you 3 say, "It's a major portion of their practice." Is that 4 part of what you mean by "qualified"? 5 A. Correct. 6 Q. In other words, for you, in this just brief 7 description of a qualified surgeon, it would be a 8 urogynecologist or gynecologist who's experienced and 9 knowledgeable in the surgical management of stress 10 urinary incontinence where it is a major portion of 11 their practice? Is that a fair definition of qualified 12 surgeon? 13 A. Yes. 14 Q. Doctor, would you think it inappropriate if 15 Ethicon would identify surgeons that were not qualified 16 and still attempt to sell these devices to those 17 surgeons? 18 MR. DIPAOLA: Object to form. 19 A. Ask it again. 20 Q. Sure. Would you deem it inappropriate, in 21 your opinion, if Ethicon knowingly attempted to sell 22 these devices to surgeons that were not qualified as you 23 describe here? 24 MR. DIPAOLA: Same objection.</p>
<p style="text-align: right;">Page 119</p> <p>1 representatives in the field serving qualified surgeons 2 that might be interested in the use of these devices," 3 correct? 4 A. Correct. 5 Q. And by "representatives in the field," you 6 mean the sales representatives from Ethicon? 7 A. The Ethicon reps in the field, yes. 8 Q. And the Ethicon reps in the field would 9 initially identify potential candidates to use these 10 devices, correct? 11 MR. DIPAOLA: Object to form. 12 A. My understanding is yes. 13 Q. And you define what you call here a qualified 14 surgeon; is that right? 15 A. Yes. 16 Q. And you say, "A qualified surgeon would be a 17 urogynecology or gynecologist who's experienced and 18 knowledgeable in the surgical management of SUI," 19 correct? 20 A. Correct. 21 Q. Is that important, do you think, that it is 22 only these -- these products are only offered to 23 qualified surgeons? 24 MR. DIPAOLA: Object to form.</p>	<p style="text-align: right;">Page 121</p> <p>1 A. Yes. 2 Q. You then start to describe what a training 3 session would look like in the next portion; is that 4 right? 5 A. That's correct. 6 Q. And is this based, Doctor, on the way that you 7 would do it? 8 A. This is the way it was done. 9 Q. And when you say "this is the way it was 10 done," you meant that this is the way Ethicon had it set 11 up to be done? 12 MR. DIPAOLA: Object to form. 13 A. They ran the programs, yes, but we had a 14 discussion as to how the training program should 15 proceed, and it was a combination of surgeon input and 16 company input. 17 Q. Did you actually work with Ethicon designing 18 the training programs? 19 A. No. 20 Q. You have presented at a number of training 21 programs, correct? 22 A. Correct. 23 Q. Have you attended other training programs 24 where you were not a presenter?</p>

<p style="text-align: right;">Page 122</p> <p>1 A. Yes.</p> <p>2 Q. Did you find that the way it was done was the</p> <p>3 same across the training programs?</p> <p>4 MR. DIPAOLA: Object to form.</p> <p>5 A. Yes. For the most part, yes.</p> <p>6 Q. Was there a difference in training programs --</p> <p>7 well, let me put it this way. You say here, "At the</p> <p>8 training program, physicians will be given information</p> <p>9 on the products, the IFUs and clinical data to review</p> <p>10 before their training session," correct?</p> <p>11 A. That was what they were supposed to do, yes.</p> <p>12 Q. Who do you mean by "they"?</p> <p>13 A. The surgeons that were coming to be trained.</p> <p>14 Q. And it's your appreciation or was your</p> <p>15 appreciation that Ethicon would send the physicians who</p> <p>16 were coming to be trained materials ahead of time to</p> <p>17 review?</p> <p>18 A. Yes, or they were given information to say</p> <p>19 "review these things."</p> <p>20 Q. You then say, "The training session would be</p> <p>21 two days, Friday night an in-depth discussion between</p> <p>22 faculty and participants about indications,</p> <p>23 contraindications, technique, complications and</p> <p>24 management of the complications," right?</p>	<p style="text-align: right;">Page 124</p> <p>1 A. Correct.</p> <p>2 Q. Describe that day in a little more detail, if</p> <p>3 you could. What happens at 7:00 a.m.?</p> <p>4 A. 7:00 a.m. we would meet in the lecture hall.</p> <p>5 And then there would be a lecture about the product, and</p> <p>6 the slides that -- the prof ed slides. And then we</p> <p>7 would answer any questions. That usually went to about</p> <p>8 9:00.</p> <p>9 And then we went into the cadaver lab. And</p> <p>10 the cadaver, depending on how many participants were</p> <p>11 there and how many faculty members were there, usually</p> <p>12 was one faculty member per cadaver and one or two</p> <p>13 participants, sometimes three, on the cadaver.</p> <p>14 And then they would implant whatever procedure</p> <p>15 that we were teaching at the time. And then we would</p> <p>16 instruct them; "You did it correctly." You did it</p> <p>17 incorrectly." They would ask, "What if this happens,</p> <p>18 what do I do? Where do I go here? What am I doing</p> <p>19 wrong?" And we would instruct them.</p> <p>20 And then we would not allow them to leave</p> <p>21 until we felt confident that what we were trying to</p> <p>22 impress upon them they understood and they had the</p> <p>23 physical technique to do it.</p> <p>24 Q. Were people from Ethicon there as well during</p>
<p style="text-align: right;">Page 123</p> <p>1 A. That would be part of the discussion, yes. It</p> <p>2 was over dinner, and then after dinner.</p> <p>3 Q. I was going to say, is that then -- so a</p> <p>4 typical training session when you say it's two days</p> <p>5 would be the Friday night dinner portion and then the</p> <p>6 Saturday portion, correct?</p> <p>7 A. The cadaver portion would be Saturday,</p> <p>8 correct.</p> <p>9 Q. Okay. And the Friday night in-depth</p> <p>10 discussion between faculty and participants is something</p> <p>11 that occurs over dinner typically?</p> <p>12 A. Correct.</p> <p>13 Q. Would these trainings occur here in</p> <p>14 Cincinnati?</p> <p>15 A. Some of them were in Cincinnati, but the</p> <p>16 majority were outside of Cincinnati.</p> <p>17 Q. Was there a particular place that you would go</p> <p>18 for them, or were they across the country?</p> <p>19 A. They were across the country.</p> <p>20 Q. Were they always nice, warm places?</p> <p>21 A. No. Sometimes cold, snowy.</p> <p>22 Q. So on the second day of the training sessions,</p> <p>23 you describe as "Saturday would be a full day in the</p> <p>24 cadaver lab, 7 a.m. to 5 p.m."</p>	<p style="text-align: right;">Page 125</p> <p>1 these training sessions?</p> <p>2 A. They were there, but they were not on the</p> <p>3 cadavers. They were in the background.</p> <p>4 Q. Was there ever a situation where you finished</p> <p>5 a day and you told Ethicon, This guy or this woman, she</p> <p>6 just doesn't have it?</p> <p>7 A. Yes, yes.</p> <p>8 Q. Do you know what happened with that physician?</p> <p>9 MR. DIPAOLA: Object to form.</p> <p>10 A. I do not.</p> <p>11 Q. Do you recall who it was?</p> <p>12 A. No.</p> <p>13 MR. DIPAOLA: I'll let that one go.</p> <p>14 Q. So in your report, you say a didactic</p> <p>15 presentation followed by a cadaver lab where every</p> <p>16 participant under the supervision of the faculty would</p> <p>17 implant the device until you were satisfied they could</p> <p>18 do it, correct?</p> <p>19 A. That's correct.</p> <p>20 Q. Is it your opinion, Doctor, that after someone</p> <p>21 has done cadaver lab to the level that you approve that</p> <p>22 person, that that person can now be qualified to go out</p> <p>23 and start using these devices?</p> <p>24 MR. DIPAOLA: Object to form.</p>

<p style="text-align: right;">Page 126</p> <p>1 A. No. I mean, it depends on their previous  2 experience. You know, if I saw and knew somebody that  3 had done, you know, Burches his or her entire career and  4 has done all these other procedures, and then I watch  5 them, I would say they would probably be qualified, but  6 that really isn't my decision, and it wasn't Ethicon's  7 decision. It was their credentialing committee at the  8 hospital to make that decision as to whether they should  9 be credentialed to perform the procedure or not.</p> <p>10 Q. Do you understand at the end of these  11 sessions, Ethicon would give each of the physicians a  12 certificate of some sort, correct?</p> <p>13 A. Yes.</p> <p>14 Q. Did you ever receive a certificate from  15 Ethicon on any of the devices?</p> <p>16 MR. DIPOLA: Object to form.</p> <p>17 A. I think I did, yes.</p> <p>18 Q. Did you provide that to your credentialing  19 committee?</p> <p>20 A. I did.</p> <p>21 Q. So those certificates were something that you  22 at least personally used to demonstrate to your hospital  23 that you were a proper physician to try these  24 techniques, correct?</p>	<p style="text-align: right;">Page 128</p> <p>1 they might have changed it, and maybe they will one day.  2 - - -  3 INVITATION BATES-STAMPED  4 ETH.MESH.00789838 WAS MARKED AS  5 EXHIBIT NO. 11.  6 - - -  7 Q. Let me just mark as Exhibit 11 -- Doctor, I've  8 handed you a document, and you see on the bottom right  9 corner it says ETH.MESH --  10 A. Yes.  11 Q. -- 00789838, correct?  12 A. Yes.  13 Q. This is from the production that was given to  14 us by Ethicon, and it's an invitation to Advanced Pelvic  15 Floor Course, Course 2. Do you see that?  16 A. Yes.  17 Q. And you are one of the faculty, correct?  18 A. I am.  19 Q. Along with --  20 A. Tamera Howell.  21 Q. Dr. Howell?  22 A. Right.  23 Q. Is this a reflection of one of the two-day  24 courses that you were discussing?</p>
<p style="text-align: right;">Page 127</p> <p>1 MR. DIPOLA: Object to form.  2 A. No. Just that I was a physician that attended  3 a two-day Ethicon-sponsored course, and I implanted the  4 device on a cadaver once or twice or three times or four  5 times.  6 Q. In some of the prof ed that you -- some of  7 these sessions that you participated in, were there  8 multiple devices actually done?  9 MR. DIPOLA: Objection.  10 Q. In other words, would you do sometimes the  11 TVT-R as well as the TVT Obturator?  12 A. Yes.  13 Q. Would those be longer courses or the same?  14 A. The same.  15 Q. Were all of the courses two days? Because  16 I've got some materials showing that maybe they weren't.  17 A. The ones that I participated in were usually  18 the two days where we came in that Friday evening and  19 had the dinner and discussion, and then Saturday was all  20 day cadavers, and usually most people departed in the  21 evenings.  22 Now, with -- I mean, that's when we used to  23 have nonstop flights most places and you could get in  24 and out quick. Now, with all this connection stuff,</p>	<p style="text-align: right;">Page 129</p> <p>1 A. No. This was a one-day course.  2 Q. Is that because it's an advanced course?  3 A. Yes, I think so.  4 Q. Okay.  5 A. If I remember right, yes.  6 Q. So if you look in the box in the bottom, it  7 says, "A representative will pick up attendees in the  8 hotel lobby at 7:00 a.m. Course will end by 2 p.m."  9 Correct?  10 A. Correct.  11 Q. So this is not a two-day course. This is  12 actually more like a half-day course; is that fair?  13 A. Correct.  14 Q. So you did participate in some of these  15 courses where at the end of the half-day course, the  16 physician would, indeed, get a certificate, correct?  17 A. But these were trained physicians that have  18 already had experience with either these devices or  19 devices from other companies that they weren't happy  20 with, and so they just wanted to compare. These were  21 not new trainees that have never done TVTs before.  22 Q. And, hence, the advanced?  23 A. Correct.  24 Q. So these would be the physicians whom Ethicon</p>



<p style="text-align: right;">Page 130</p> <p>1 representatives, sales representatives, have identified</p> <p>2 as more qualified than a first timer, for example, and</p> <p>3 so you could do a shorter course?</p> <p>4 MR. DIPAOLA: Object to form.</p> <p>5 A. Or the surgeon could have contacted Ethicon as</p> <p>6 well. It doesn't necessarily have to be the rep. The</p> <p>7 surgeon could say, hey, I'm doing these procedures with</p> <p>8 this device. I'm not happy with it. Do you have any</p> <p>9 advanced courses where we can learn or at least see what</p> <p>10 your products are like?</p> <p>11 Q. But it's your testimony that this was not the</p> <p>12 norm for professional education?</p> <p>13 A. This was not, correct, and usually there's</p> <p>14 more than just two faculty members as well on the norm,</p> <p>15 the bigger ones.</p> <p>16 - - -</p> <p>17 INVITATION BATES-STAMPED</p> <p>18 ETH.MESH.01678144 WAS MARKED AS</p> <p>19 EXHIBIT NO. 12.</p> <p>20 - - -</p> <p>21 Q. I'm going to hand you Exhibit 12. It's</p> <p>22 another flyer for Advanced Pelvic Floor Course.</p> <p>23 A. Okay.</p> <p>24 Q. And, indeed, this one has more than two</p>	<p style="text-align: right;">Page 132</p> <p>1 work, correct?</p> <p>2 A. Correct.</p> <p>3 Q. How would you bill for that? Is it an hourly</p> <p>4 billing, or is it by day?</p> <p>5 A. It was a set fee.</p> <p>6 Q. It was a set fee?</p> <p>7 A. It was a set fee.</p> <p>8 Q. No matter how many hours you put in?</p> <p>9 A. Correct, yeah.</p> <p>10 MR. DIPAOLA: Asked and answered.</p> <p>11 - - -</p> <p>12 SPREADSHEET BATES-STAMPED</p> <p>13 ETH.MESH.04181701 WAS MARKED AS</p> <p>14 EXHIBIT NO. 13.</p> <p>15 - - -</p> <p>16 Q. I'm going to hand you what is being marked as</p> <p>17 Exhibit 13. Doctor, I've handed you what has been</p> <p>18 marked as Exhibit 13.</p> <p>19 A. Okay.</p> <p>20 Q. It's a spreadsheet that was produced to us by</p> <p>21 Ethicon, and it lists preceptors. Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. Then it has the event date; is that right?</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 131</p> <p>1 trainers, correct?</p> <p>2 A. Correct.</p> <p>3 Q. And this was another half-day course, correct?</p> <p>4 A. This was.</p> <p>5 MR. DIPAOLA: Objection.</p> <p>6 A. Actually, it was a full-day course. It went</p> <p>7 to 3:15. I would consider that a full-day course.</p> <p>8 Q. Where it says "A representative will pick up</p> <p>9 attendees in the hotel lobby at 7:30. Course will end</p> <p>10 by 3:15."</p> <p>11 A. 3:15.</p> <p>12 Q. Were you the one deciding how long the course</p> <p>13 should be?</p> <p>14 A. No.</p> <p>15 Q. Who decided that?</p> <p>16 A. The company.</p> <p>17 Q. Would you consider a full day to be an</p> <p>18 eight-hour billing for you?</p> <p>19 A. An eight-hour billing?</p> <p>20 MR. DIPAOLA: Object to form.</p> <p>21 Q. Let me ask that better.</p> <p>22 For Exhibit 12 that we were just looking at --</p> <p>23 A. Yes.</p> <p>24 Q. -- you would be paid by Ethicon for doing that</p>	<p style="text-align: right;">Page 133</p> <p>1 Q. This is for a time frame of 2008. That's most</p> <p>2 of the dates, correct?</p> <p>3 A. Yes.</p> <p>4 Q. Then it has the event name, the location, the</p> <p>5 time spent, the amount paid, and the date that the</p> <p>6 payment was sent to the preceptor, correct?</p> <p>7 A. Correct.</p> <p>8 Q. If you go down this list, for example, and you</p> <p>9 look at just the "Prolift/SECUR cadaver lab," so the</p> <p>10 fourth line down. It's actually Brian Flynn from</p> <p>11 Denver, Colorado, right?</p> <p>12 A. Yes.</p> <p>13 Q. It has six physicians, I think. Yes, six</p> <p>14 physicians who taught at that lab on 4/2/2008, correct?</p> <p>15 A. Okay. Yes.</p> <p>16 Q. You'll see to the right it says, "Time spent,</p> <p>17 eight hours" on each of those, right?</p> <p>18 A. Correct.</p> <p>19 Q. So would that be in your --</p> <p>20 A. Well, no, it says Flynn was only there for</p> <p>21 four hours, and then Easter was there for eight, and</p> <p>22 Aguirre was there for eight.</p> <p>23 Q. You know all those guys, right?</p> <p>24 A. I know Aguirre and Mike Woods. I've met</p>

<p style="text-align: right;">Page 134</p> <p>1 Brian, but I wouldn't say I know him. I don't know Tom  2 Easter.  3 Q. I met Brian last week, just like this.  4 MR. DIPOLA: Just a point of accuracy, this  5 is not on the same event date. The 4/3 and 4/7 are  6 Easter and Aguirre. The rest are not on 4/2 -- the rest  7 are on 4/2. Easter and Aguirre are not on 4/2, so I'm  8 not quite what you're asking.  9 Q. If you turn to the last page, Doctor, six  10 down, I think you'll recognize that name.  11 A. The last page, six down, I have no idea who  12 that is. Who is that?  13 MR. DIPOLA: Just I think --  14 THE WITNESS: Yeah, I know.  15 MR. DIPOLA: You were kidding. I thought you  16 were on the wrong page.  17 A. Yes. I see it.  18 Q. Six down, and that's you, correct?  19 A. That's me, that's correct.  20 Q. So this appears to report that on  21 February 18th, 2009, you taught a TVT-O preceptorship in  22 Cincinnati, Ohio, correct?  23 A. That is correct.  24 Q. And it shows four hours, and a billing of</p>	<p style="text-align: right;">Page 136</p> <p>1 by the time we got there.  2 So it's fair to say, Doctor, if we turn back  3 to your report, Exhibit 2, that in the section where  4 you're discussing training and you're discussing a  5 two-day training session, that your recollection is that  6 that's for essentially first-time surgeons; is that  7 fair?  8 A. First-time surgeons that are using other  9 techniques and want to learn or be educated on TVT.  10 Q. And those would be the two-day seminars. For  11 more advanced surgeons, those seminars could be as short  12 as a half day?  13 A. Correct.  14 Q. And they would all receive a certificate that  15 they could provide to their credentialing board?  16 MR. DIPOLA: Object to form.  17 A. One would be only for four hours. The other  18 would be for --  19 Q. You go on to discuss what we were just talking  20 about, surgeon credentialing, and then on to adequacy of  21 company IFU and patient brochures.  22 A. Right.  23 Q. And I think we discussed earlier that in the  24 three or so months leading up to drafting your report</p>
<p style="text-align: right;">Page 135</p> <p>1 \$1,750, correct?  2 A. Correct.  3 Q. Is that consistent with your memory of how you  4 would do preceptorships? They would be about four  5 hours, and that was your pay for a preceptorship?  6 MR. DIPOLA: Object to form.  7 A. Yes. But if I remember right, this was a  8 little different. This was a group of surgeons that  9 came in. This was a program that we did here where we  10 brought them in that night, if I remember right. Yeah,  11 because these are the only ones I did in Cincinnati,  12 unless -- well, maybe not.  13 But we were doing proctorships or bringing  14 surgeons in to watch me do surgery, and then we would go  15 over -- so we'd do a half day in the OR, and they would  16 actually watch me in the OR. And then we would go over  17 to UC and do the cadaver lab, and so that would only be  18 four hours. That's different than these programs.  19 Q. Because these are the preceptorships?  20 A. These were more the doctors wanted to see the  21 surgery being done in person.  22 Q. And then you appear again --  23 A. I don't see me again.  24 Q. It's on a different page. It would be complex</p>	<p style="text-align: right;">Page 137</p> <p>1 and in the drafting of your report, you didn't  2 necessarily review any IFUs or patient brochures during  3 that time frame, correct?  4 A. Correct.  5 Q. When you're writing your opinions here about  6 the IFU and the patient brochures, are those based upon  7 your historical experience with those documents?  8 A. Yes.  9 MR. DIPOLA: Object to form.  10 Q. They weren't specifically reviewed for  11 drafting of your report; is that fair?  12 MR. DIPOLA: Object to form.  13 A. Correct.  14 Q. And there again in this section, you have a  15 statement, "All patients are consented and understand  16 the risk, benefits, options and complications."  17 A. Correct.  18 Q. Again, that's not something that you know for  19 an absolute fact that all patients are consented, nor do  20 you know for a fact that all patients understand,  21 correct?  22 A. Well, I --  23 Q. I have to ask.  24 A. Yeah, and I have to answer. Yes, all patients</p>



<p style="text-align: right;">Page 138</p> <p>1 are consented; otherwise, they can't go into surgery.</p> <p>2 Every patient has to be consented.</p> <p>3 Q. In your practice?</p> <p>4 A. In any practice. Nobody can go into the OR in</p> <p>5 the United States without a consent form being signed by</p> <p>6 the patient; or if they can't sign it, whoever is</p> <p>7 responsible for them. So they are consented.</p> <p>8 Now, I know for a fact that all these teaching</p> <p>9 programs that we had, we always spoke about consent, how</p> <p>10 to consent somebody, what you have to tell them, et</p> <p>11 cetera, et cetera. So, no, I have not talked to every</p> <p>12 surgeon and say, "Do they consent this way?" But I</p> <p>13 would say there's a uniform acceptance of a consent form</p> <p>14 when it comes to a synthetic sling.</p> <p>15 Q. So, again, we've discussed that you haven't</p> <p>16 looked at any internal Ethicon documents, nor have you</p> <p>17 read any of the Ethicon employee depositions, correct?</p> <p>18 A. Correct.</p> <p>19 MR. DIPAOLA: Object.</p> <p>20 Q. So, you know, if one of Ethicon's employees</p> <p>21 had testified that she would receive telephone calls</p> <p>22 from women who would say, "I had no idea that I could</p> <p>23 have permanent pain every time I have sexual</p> <p>24 intercourse. Nobody ever told me that." You don't have</p>	<p style="text-align: right;">Page 140</p> <p>1 Q. But it's your opinion that they all understand</p> <p>2 that consent? That's what you say in your expert</p> <p>3 report, correct?</p> <p>4 MR. DIPAOLA: Object to form.</p> <p>5 A. Yes.</p> <p>6 Q. And is it your opinion that if a woman says</p> <p>7 that she didn't understand the risks, that she's lying?</p> <p>8 MR. DIPAOLA: Object to form.</p> <p>9 A. No, I didn't say that. I'm saying that she</p> <p>10 might not have understood what they were telling her.</p> <p>11 But when you consent somebody, you list all the possible</p> <p>12 complications that could be occurring, and you do that</p> <p>13 both in a mesh and a non-mesh procedure.</p> <p>14 (Discussion held off the record.)</p> <p>15 MR. ZONIES: I'll reserve my two minutes if</p> <p>16 you're going to have questions.</p> <p>17 MR. DIPAOLA: I have maybe five minutes'</p> <p>18 worth.</p> <p>19 MR. ZONIES: That's great.</p> <p>20 - - -</p> <p>21 EXAMINATION</p> <p>22 BY MR. DIPAOLA:</p> <p>23 Q. Dr. Karram, just going over some points that</p> <p>24 Plaintiff counsel was asking you over the last three</p>
<p style="text-align: right;">Page 139</p> <p>1 any way to know whether or not she was actually properly</p> <p>2 consented --</p> <p>3 MR. DIPAOLA: Objection.</p> <p>4 Q. -- correct?</p> <p>5 MR. DIPAOLA: Total hearsay. Assumes facts</p> <p>6 not in evidence. You could go on and on.</p> <p>7 A. I could say the same thing. I have a patient</p> <p>8 come to me. I do an exam. She doesn't have a uterus.</p> <p>9 I say, "When did you have a hysterectomy?" She says, "I</p> <p>10 didn't even know I had a hysterectomy." Was she</p> <p>11 consented correctly for her hysterectomy?</p> <p>12 Q. Would it be fair then to say she didn't</p> <p>13 understand that she had a hysterectomy?</p> <p>14 MR. DIPAOLA: Object to form.</p> <p>15 A. No. I think it's fair to say that probably</p> <p>16 they are not either telling the truth, or they</p> <p>17 misrepresent the truth, or they're trying to get</p> <p>18 something else out of whatever they're trying to</p> <p>19 discuss.</p> <p>20 But, no, I think anybody who has surgery has</p> <p>21 to be consented. And if you remember, the FDA came out</p> <p>22 with a notice in 2008 and 2011, and both of those had</p> <p>23 something to do with consent. So patients have to be</p> <p>24 consented, and they are consented.</p>	<p style="text-align: right;">Page 141</p> <p>1 hours minus two minutes, is it your opinion that Ethicon</p> <p>2 bears no responsibility to decide who is qualified to do</p> <p>3 a particular procedure, and, indeed, that responsibility</p> <p>4 lies with the individual hospital's credentialing</p> <p>5 committee?</p> <p>6 MR. ZONIES: Object to form.</p> <p>7 A. Yes.</p> <p>8 Q. Remember when Plaintiff's counsel was</p> <p>9 questioning you about the Ulmsten report?</p> <p>10 A. Yes.</p> <p>11 Q. And, if you will, questions were put forth</p> <p>12 that the representation in your general report of a</p> <p>13 slide in the Ulmsten paper had some parallax -- my word,</p> <p>14 not his -- had some parallax issues, correct?</p> <p>15 A. Correct.</p> <p>16 Q. If one goes to the original Ulmsten chart on</p> <p>17 page 349 of that study and the numbers that are above</p> <p>18 the bar graphs between the 12-month success rates and</p> <p>19 the 24/36-month success rates, are those numbers the</p> <p>20 same?</p> <p>21 A. They are.</p> <p>22 Q. Would that imply to you that at least for the</p> <p>23 36 months that this study was represented by this bar</p> <p>24 graph, that the repairs were essentially stable over the</p>

<p style="text-align: right;">Page 142</p> <p>1 years between 12 months and 36 months?</p> <p>2 MR. ZONIES: Object to form.</p> <p>3 A. Yes.</p> <p>4 Q. Do you remember the TOMUS study?</p> <p>5 A. Yes.</p> <p>6 Q. Would you agree with me that the TOMUS study</p> <p>7 was -- and Plaintiff's counsel used the equivalency</p> <p>8 terminology. This study was a study that attempted to</p> <p>9 decide the difference, if any, between TVT-R and TVT-O</p> <p>10 when used to correct stress urinary incontinence; would</p> <p>11 that be a fair statement?</p> <p>12 A. That would, yes.</p> <p>13 Q. This study was in no way designed to decide</p> <p>14 whether mesh tapes in midurethral sling positions were</p> <p>15 any better or worse than any preceding operations that</p> <p>16 did not include mesh, correct?</p> <p>17 A. That's correct.</p> <p>18 Q. And, indeed, what the study really found was</p> <p>19 that the benefits of TVT-R carried over to TVT-O when</p> <p>20 they were compared head to head?</p> <p>21 MR. ZONIES: Object to form.</p> <p>22 A. That's correct, with less complications.</p> <p>23 Q. Do you remember when Plaintiffs' counsel also</p> <p>24 asked you whether you were a biomaterials expert?</p>	<p style="text-align: right;">Page 144</p> <p>1 materials, correct?</p> <p>2 A. I am not.</p> <p>3 Q. You say in your last sentence on the next page</p> <p>4 in that section, "They should be considered safe until</p> <p>5 scientific data proves otherwise." Do you believe that</p> <p>6 to be the standard of how to determine the safety of a</p> <p>7 medical device?</p> <p>8 MR. DIPAOLA: Object to form.</p> <p>9 A. Come again?</p> <p>10 Q. Do you believe your statement that "They</p> <p>11 should be considered safe until scientific data proves</p> <p>12 otherwise," do you believe that to be the standard by</p> <p>13 which you would judge the safety of a medical device?</p> <p>14 MR. DIPAOLA: Object to form; misstates.</p> <p>15 A. You have to go by the evidence and the data</p> <p>16 that you have at this time. And based on the data that</p> <p>17 we have at this time, there is no evidence to show that</p> <p>18 there's any carcinogenesis related to these slings.</p> <p>19 Q. Is it your opinion --</p> <p>20 A. Now, maybe in 10 years or 15 or 20 years,</p> <p>21 something else might show up that's different. That's</p> <p>22 what I'm implying when I say that statement.</p> <p>23 Q. Fair enough. Thank you for your time, Doctor.</p> <p>24 A. Anytime.</p>
<p style="text-align: right;">Page 143</p> <p>1 A. Yes.</p> <p>2 Q. Do you remember what you answered to that?</p> <p>3 A. I said no.</p> <p>4 Q. Whereas you're not a biomaterials expert, as</p> <p>5 an expert urogynecologist who has implanted, in your</p> <p>6 words, over 2,000 slings, are you an expert in how a</p> <p>7 woman's body reacts to implanted mesh?</p> <p>8 MR. ZONIES: Object to form.</p> <p>9 A. I would consider myself an expert, yes.</p> <p>10 Q. As you sit here today, do you believe that</p> <p>11 midurethral slings are the gold standard of current</p> <p>12 therapy in treating women with stress urinary</p> <p>13 incontinence?</p> <p>14 MR. ZONIES: Object to the form.</p> <p>15 A. Yes.</p> <p>16 MR. DIPAOLA: I have nothing else.</p> <p>17 - - -</p> <p>18 FURTHER EXAMINATION</p> <p>19 BY MR. ZONIES:</p> <p>20 Q. Doctor, just a follow-up. In the next section</p> <p>21 of your report it's entitled, "Malignant Potential of</p> <p>22 Mesh." Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. You are not an expert in carcinogenicity of</p>	<p style="text-align: right;">Page 145</p> <p>1 MR. DIPAOLA: We're not going to waive.</p> <p>2 (Signature not waived.)</p> <p>3 - - -</p> <p>4 Thereupon, at 2:36 p.m., on Tuesday, March 29,</p> <p>5 2016, the deposition was concluded.</p> <p>6 - - -</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

Michael Karram, M.D.

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1           ACKNOWLEDGMENT OF DEPONENT

2

3           I, \_\_\_\_\_, do

4 hereby certify that I have read the

5 foregoing pages, and that the same

6 is a correct transcription of the answers

7 given by me to the questions therein

8 propounded, except for the corrections or

9 changes in form or substance, if any,

10 noted in the attached Errata Sheet.

11

12 \_\_\_\_\_

13 MICHAEL KARRAM, M.D.           DATE

14

15 Subscribed and sworn

16 to before me this

17 \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

18 My commission expires: \_\_\_\_\_

19 \_\_\_\_\_

20 Notary Public

21

22

23

24

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4           PAGE LINE CHANGE

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1           CERTIFICATE

2           STATE OF OHIO   :

3           SS:

4           COUNTY OF FRANKLIN :

5           I, Carol A. Kirk, a Registered Merit Reporter

6 and Notary Public in and for the State of Ohio, duly

7 commissioned and qualified, do hereby certify that the

8 within-named MICHAEL KARRAM, M.D., was by me first duly

9 sworn to testify to the truth, the whole truth, and

10 nothing but the truth in the cause aforesaid; that the

11 deposition then given by him was by me reduced to

12 stenotype in the presence of said witness; that the

13 foregoing is a true and correct transcript of the him so

14 given by him; that the deposition was taken at the time

15 and place in the caption specified and was completed

16 without adjournment; and that I am in no way related to

17 or employed by any attorney or party hereto or

18 financially interested in the action; and I am not, nor

19 is the court reporting firm with which I am affiliated,

20 under a contract as defined in Civil Rule 28(D).

21

22           IN WITNESS WHEREOF, I have hereunto set my

23 hand and affixed my seal of office at Columbus, Ohio on

24 this 1st day of April 2016.

25

26           \_\_\_\_\_

27           CAROL A. KIRK, RMR

28           NOTARY PUBLIC - STATE OF OHIO

29           My Commission Expires: April 8, 2017.

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